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National Vaccine Injury Compensation Program: Financing the Post-1988 Program and Other Issues

A Report to The Congress

Department of the Treasury
August 1994

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A Report to the Congress

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DEPARTMENT OF THE TREASURY
WASHINGTON

ASSISTANT SECRETARY

August 10, 1994

The Honorable Sam Gibbons
Acting Chairman
Committee on Ways and Means
United States House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

The Conference Report on H.R. 2264 (Public Law 103-66), the Omnibus Budget Reconciliation Act of 1993, provides that the Secretary of the Treasury, in consultation with the Secretary of Health and Human Services, conduct a study of the Vaccine Injury Compensation Trust Fund and several related matters and submit a report of that study to the House Committee on Ways and Means and the Senate Committee on Finance within one year after the date of enactment.

Pursuant to that Conference Report, I hereby submit "Vaccine Injury Compensation: Financing the Post-1988 Program and Other Issues."

I hope you will find this report informative. I am sending a similar letter to Representative Bill Archer.

Sincerely,

Leslie Samuels

Leslie B. Samuels
Assistant Secretary
(Tax Policy)

DEPARTMENT OF THE TREASURY
WASHINGTON

ASSISTANT SECRETARY

August 10, 1994

The Honorable Daniel Patrick Moynihan
Chairman
Committee on Finance
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

The Conference Report on H.R. 2264 (Public Law 103-66), the Omnibus Budget Reconciliation Act of 1993, provides that the Secretary of the Treasury, in consultation with the Secretary of Health and Human Services, conduct a study of the Vaccine Injury Compensation Trust Fund and several related matters and submit a report of that study to the House Committee on Ways and Means and the Senate Committee on Finance within one year after the date of enactment.

Pursuant to that Conference Report, I hereby submit "Vaccine Injury Compensation: Financing the Post-1988 Program and Other Issues."

I hope you will find this report informative. I am sending a similar letter to Senator Bob Packwood.

Sincerely,

Leslie Samuels

Leslie B. Samuels
Assistant Secretary
(Tax Policy)

EXECUTIVE SUMMARY

The National Vaccine Injury Compensation Program (VICP) was made permanent by the Omnibus Budget Reconciliation Act of 1993 (OBRA '93). For vaccinations occurring after September 30, 1988, VICP compensates for injuries and deaths associated with vaccines routinely administered to children. Compensation is paid out of a trust fund supported by excise taxes levied on vaccine manufacturers.

The Conference Report on OBRA '93 mandated that the Secretary of the Treasury, in consultation with the Secretary of Health and Human Services, conduct a study of several specific aspects of VICP and its financing. This report is rendered in response to that mandate. The major findings of the report are as follows:

- VICP compensation awards are expected to be $55 million per year during the latter half of the 1990s. VICP has not been in existence long enough to project future outlays with confidence. All cases arising from vaccinations in the first full year of operation have yet to be adjudicated. As the program matures sufficient program data will become available to permit more sophisticated methods of estimating future outlays to be used.

- The scientific literature indicates that most injuries and deaths of a type compensable under VICP cannot be said with certainty to have been caused by vaccines covered by VICP. VICP awards are extremely rare in comparison to the number of vaccines administered.

- The principle of imposing excise taxes on vaccine manufacturers to support a trust fund used to compensate victims of adverse effects associated with vaccinations is sound.

- The Secretary of Health and Human Services is expected to add hepatitis B and Hib vaccines to VICP's Vaccine Injury Table. Following this action, taxes on these vaccines should be enacted so that any related adverse events are covered by VICP.

- Current tax rates on vaccines generate more revenue than needed to support the Vaccine Trust Fund. Based on current projections, the trust fund balance will be about $1.2 billion by the year 2000. Rates could be cut roughly in half and still retain a trust fund balance sufficient to cover an unexpected increase in VICP awards.

- Vaccines produced by State governments should be taxed on the same basis as vaccines produced by private companies.

- As an alternative to maintaining the current risk-related method of setting tax rates on each vaccine covered by VICP, Congress may need to consider a flat-rate tax on all covered vaccines because changing vaccine technology and other factors may make risk assessment problematic.

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CHAPTER 1. INTRODUCTION AND SUMMARY

I. INTRODUCTION

A. Congressional Mandate

The Conference Report on H.R. 2264 (Public Law 103-66), the Omnibus Budget Reconciliation Act of 1993 (OBRA '93), provides that the Secretary of the Treasury, in consultation with the Secretary of Health and Human Services (HHS), conduct a study of the Vaccine Injury Compensation Trust Fund and several related matters and submit a report of that study to the House Committee on Ways and Means and the Senate Committee on Finance within one year after the date of enactment.[1] The Conference Report referenced the House bill which directed that the following items be studied:

1) The estimated amount that will be paid from the Vaccine Injury Compensation Trust Fund with respect to vaccines administered after September 30, 1988;

2) The rates of vaccine-related injury or death with respect to various types of vaccines;

3) New vaccines and immunization practices being developed or used for which amounts may be paid from the Trust Fund;

4) Whether additional vaccines should be included in the National Vaccine Injury Compensation Program; and

5) The appropriate treatment of vaccines produced by State governmental agencies.

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[1] H.R. Rept. 103-213, August 4, 1993, pp. 730-33. OBRA '93 was enacted August 10, 1993. The Report of the House Committee on the Budget indicated that the mandated report should "determine whether additional vaccines should be included in the Program or other modifications (such as adjustments to the excise tax rates) are warranted." H.R. Rept. 103-111, p. 810.

B. Description of the National Vaccine Injury Compensation Program (VICP)

VICP is a no-fault alternative to State tort law and private liability insurance systems for compensating individuals, including adults, who have been injured by vaccines routinely administered to children. It was established by the National Childhood Vaccine Injury Act of 1986, title III of P.L. 99-660 (the 1986 Act), enacted on November 14, 1986.[2]

VICP was established to improve the then current approach to compensating individuals damaged by a vaccine, and to improve the stability and predictability of the childhood vaccine market. The legislative history of the 1986 Act states, in part:

> ...for the relatively few who are injured by vaccines -- through no fault of their own -- the opportunities for redress and restitution are limited, time-consuming, expensive, and often unanswered. Currently, vaccine-injured persons can seek recovery for their damages only through the civil tort system or through a settlement arrangement with the vaccine manufacturer. Over time, neither approach has proven satisfactory. Lawsuits and settlement negotiations can take months and even years to complete. Transaction costs -- including attorneys' fees and court payments -- are high. And in the end, no recovery may be available. Yet futures have been destroyed and mounting expenses must be met.
>
> Manufacturers have become concerned not only with the problems of time and expense, but with the issue of the availability of affordable product liability insurance that is used to cover losses related to vaccine injury cases. Whether current problems with liability insurance arise from a crisis in the tort system or from a particularly bad downturn in the business cycle of the insurance industry has been and remains a matter of great controversy. Nevertheless, there is little doubt that vaccine manufacturers face great difficulty in obtaining insurance. This lack of insurance was the stated reason for one manufacturer to withdraw temporarily from the vaccine market in 1984. Others have suggested that they may follow a similar course of action. This factor, coupled with the possibility that vaccine-injured persons may recover substantial awards in tort claims, has prompted manufacturers to question their continued participation in the vaccine market.
>
> The loss of any of the existing manufacturers of childhood vaccines at this time could create a genuine public health hazard in this country. Currently, there is only one manufacturer of the polio vaccine, one manufacturer of the measles, mumps, rubella (MMR) vaccine, and two manufacturers of the DPT vaccine.

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[2] The VICP provisions of the 1986 Act, as subsequently amended, appear as Subtitle 2 of Title XXI of the Public Health Service Act (title 42 United States Code).

> Two states, Michigan and Massachusetts, produce their own DPT vaccine. Despite Congressional support, Federal vaccine stockpiles maintained by the Centers for Disease Control [and Prevention] (CDC) have never reached CDC's recommended level of six-months' supply. Thus, the withdrawal of even a single manufacturer would present the very real possibility of vaccine shortages, and, in turn, increasing numbers of unimmunized children, and, perhaps, a resurgence of preventable diseases.[3]

The Vaccine Injury Compensation Trust Fund (the Vaccine Trust Fund) was created by the Omnibus Budget Reconciliation Act of 1987 (OBRA '87) to provide an appropriate funding mechanism for the ongoing portion of VICP. Prior to being made permanent by OBRA '93, compensation payments only with respect to injuries and deaths from vaccines administered after September 30, 1988, and before October 1, 1992, were to be paid out of the Vaccine Trust Fund. In addition to compensation payments for injuries and deaths, attorney fees and certain administrative costs of VICP are also paid out of the Vaccine Trust Fund.

Trust Fund Revenues. Net revenues from excise taxes imposed on certain vaccines are transferred into the Vaccine Trust Fund. In addition, interest income is received by the Vaccine Trust Fund on fund balances invested in special-issue Treasury securities. The excise taxes are imposed on the following vaccines, at the following per-dose rates:[4]

Diphtheria, pertussis, and tetanus (DPT)	$4.56
Diphtheria and tetanus (DT)	0.06
Measles, mumps, and rubella (MMR)	4.44
Polio	0.29

Gross excise tax receipts are reduced by 25 percent before being transferred from the General Fund (into which these excise taxes are initially deposited) to the Vaccine Trust Fund. This reduction follows the statutory requirement in OBRA '87 that net revenues be transferred and committee report language indicating that a 25 percent factor be used to account for the

---

[3] H.R. Rept. 99-908, Part I, September 26, 1986, pp. 6-7.

[4] These excise taxes became effective for vaccines sold after December 31, 1987. If a vaccine includes more than one of the enumerated vaccines then the tax on the combination vaccine is the sum of the taxes separately imposed on the components. A single-antigen vaccine (e.g., for measles) is taxed at the rate applicable to the taxable vaccine of which the single antigen is a part (e.g., $4.44 per dose for a measles vaccine).

reduction in income and payroll tax receipts resulting from imposition of an excise tax.[5] Exported vaccines are not subject to these excise taxes.[6]

As provided in OBRA '87, the excise taxes supporting the Vaccine Trust Fund expired after December 31, 1992, as a result of the Treasury Secretary's determination that the Trust Fund balance was sufficient to compensate individuals for the adverse effects of vaccines administered after September 30, 1988, and before October 1, 1992.[7]

Pre-1988 Program. Compensation for injuries related to vaccines administered prior to October 1, 1988, is paid out of General Fund appropriations. This "Pre-1988 Program" component of VICP is limited to claims filed before February 1, 1991 and is not further discussed in this report; a *Fact Sheet* regarding that program appears in Appendix A.

Compensation Under the Post-1988 Program. To qualify for compensation from the Vaccine Trust Fund a petitioner must either prove that the vaccine caused the death or injury, or that a death or injury set forth in the Vaccine Injury Table occurred within the time periods specified in the Table. Additional information regarding the "Post-1988 Program" component of VICP is provided in a Health Resources and Services Administration *Fact Sheet*, which appears in Appendix A. The Vaccine Injury Table appears in Appendix B.

An individual is, in general, barred from bringing a civil action in State or Federal court against a vaccine manufacturer or administrator for damages in excess of $1,000 (or in an unspecified amount) arising from a vaccine administered after September 30, 1988. The courts are barred from awarding amounts in excess of $1,000 for such damages, unless a petition has been filed for compensation under VICP for such injury or death, the U.S. Court of Federal Claims has issued a judgment on such petition, and the petitioner files an election to file a civil action or withdraw the petition.

---

[5] The 25 percent factor is the standard offset used when excise tax provisions are scored for budget purposes during the legislative process. Budget estimating conventions are that gross domestic product (GDP) and the price level are fixed. Excise and other indirect business taxes are a wedge between GDP and payments to labor and capital (wages and other employee compensation, interest, profits, and rents). Thus an increase in excise taxes, with GDP and the price level fixed, must reduce payments to labor and capital (the "offset"), and therefore reduce income and payroll taxes. The Vaccine Trust Fund is the only trust fund financed with dedicated excise taxes where net, rather than gross, excise tax revenues are transferred from the General Fund.

[6] Exports to U.S. possessions are taxed and residents of U.S. possessions are covered by VICP.

[7] Treasury Announcement 93-11, January 25, 1993.

A petition for compensation under VICP must show that the person who suffered the injury, or who died, received a taxable vaccine set forth in the Vaccine Injury Table or contracted polio from another person who received an oral polio vaccine. A petition must also show that the person sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table, or died from the administration of the vaccine, and the first symptom or manifestation of that condition occurred within the time period after vaccine administration set forth in the Vaccine Injury Table.

A petition does not require evidence proving a causal relationship between vaccine administration and an adverse reaction. However, a petition may provide evidence supporting a causal relationship between a listed vaccine and an adverse reaction specified in the Vaccine Injury Table occurring outside the time periods specified in the Table. A petition may also provide evidence supporting a causal relationship between a listed vaccine and an adverse reaction not specified in the Vaccine Injury Table.

In addition, the petition must show that the person (i) suffered the residual effects or complications of such illness, disability, injury, or condition for more than six months after the administration of the vaccine; (ii) incurred unreimbursable expenses due in whole or in part to such illness, disability, injury, or condition in an amount greater than $1,000, or (iii) died from the administration of the vaccine. Finally, the petition must show that the petitioner has not previously collected an award or settlement of a civil action for damages for such vaccine-related injury or death.

Petitions must be filed within 36 months after the date of the first symptom of a vaccine-related injury. Petitions with respect to a death must be filed within 24 months from the date of the death, and within 48 months after the date of the first symptom of the injury resulting in death.

The U.S. Court of Federal Claims has jurisdiction over the proceedings to determine if a petitioner is entitled to compensation under the program and the amount of the compensation. In general, a person files a petition in the U.S. Court of Federal Claims naming the Secretary of Health and Human Services as the respondent. Following receipt of the petition, the U.S. Court of Federal Claims designates a special master who has the authority to require written information or testimony and to conduct hearings as may be appropriate for the preparation of proposed findings of fact and conclusions of law with respect to whether compensation is to be provided under VICP and the amount of the compensation.

VICP provides compensation for the following costs associated with the adverse effects of vaccines administered after September 30, 1988:

- Actual and reasonable projected unreimbursable expenses before and after the date of judgment, including expenses which result from the vaccine-related injury, expenses incurred by or on behalf of the person who suffered the injury, expenses for diagnosis and medical or other remedial care, and expenses for rehabilitation,

developmental evaluation, special education, vocational training and placement, case management services, counseling, emotional or behavioral therapy, residential and custodial care and service expenses, special equipment, related travel, and facilities;

- Actual and anticipated loss of earnings after the age of 18;

- Actual and projected pain and suffering and emotional distress from the vaccine-related injury, not to exceed $250,000;

- $250,000 for the estate of the deceased in the case of a vaccine-related death; and

- Reasonable attorney fees and other costs incurred in any proceeding on a petition, even if no other compensation is provided under VICP.

After the judgment of the U.S. Court of Federal Claims or the appellate court, the petitioner files either an election to receive compensation (if compensation was awarded) or to accept the judgment (if compensation was not awarded), or an election to file a civil action. If the election is not filed within 90 days from the date of judgment, the petitioner is deemed to have filed an election to accept the judgment of the court.

VICP compensation is secondary to all insurance coverage except Medicaid. Compensation payments for injury awards are usually paid in the form of an annuity purchased from an insurance company. Death awards are paid as a lump sum.

Modifications to the Vaccine Injury Table. The 1986 Act granted the Secretary of HHS authority to promulgate regulations modifying the Vaccine Injury Table. Such modifications may involve adding or removing injuries, disabilities, illnesses, conditions, and deaths for which compensation may be provided or changing the time periods during which the first symptom or manifestation of the onset or the significant aggravation of any such injury, disability, illness, condition, or death must occur. That authority did not extend to adding new vaccines to the list of vaccines covered by VICP.

Based on an Institute of Medicine (IOM) study of the adverse effects of the pertussis and rubella vaccines, the Secretary of HHS promulgated proposed changes to the Vaccine Injury Table on August 14, 1992.[8] Final regulations modifying the Vaccine Injury Table in response to the IOM study had not been issued as of July 31, 1994. A second IOM report, released in September 1993, studied the remaining vaccines on the Vaccine Injury Table, as well as hepatitis B and Hib vaccines. During 1994, The Secretary of HHS is expected to begin the rulemaking process to further modify the Table, using this second IOM report as a key document addressing the adverse events that may be related to these vaccines.

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[8] Federal Register, Vol.57, No. 158, August 12, 1992, pp. 36878-85.

C. Amendments Made by OBRA '93

OBRA '93 permanently extended the excise taxes on the four categories of vaccines, effective August 10, 1993. It also authorized compensation to be paid from the Vaccine Trust Fund under VICP for certain damages resulting from vaccines administered after September 30, 1988, without respect to the October 1, 1992 cutoff date contained in OBRA '87.

OBRA '93 required the Secretary of HHS to revise the Vaccine Injury Table to include: 1) vaccines which are recommended to the Secretary by the Centers for Disease Control and Prevention (CDC) for routine administration to children; 2) the injuries, disabilities, illnesses, conditions, and deaths associated with such vaccines; and 3) the time period in which the first symptoms or manifestations of onset or other significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths associated with such vaccines may occur. With respect to CDC recommendations made prior to August 1, 1993, the Vaccine Injury Table is to be revised by the Secretary of HHS prior to August 1, 1995. With respect to CDC recommendations made after August 1, 1993 the Secretary is required to revise the Vaccine Injury Table within two years of such recommendation. Under the terms of OBRA '93, those vaccinated with vaccines added to the Vaccine Injury Table pursuant to this administrative procedure are not covered by VICP until taxes on those vaccines are enacted.

II. SUMMARY

This report addresses the issues of future outlays and rates of vaccine-related deaths and injuries that the Congress directed to be studied by analyzing financial and programmatic data relating to petitions filed seeking compensation for injuries and deaths which petitioners attributed to vaccinations occurring after September 30, 1988. In particular, data are analyzed regarding petitions filed with respect to vaccinations administered in 1989, the first full year the Post-1988 Program operated. This analysis provides information regarding future outlays for compensation from the Vaccine Trust Fund and rates of injury and death associated with particular vaccines.

The report notes that the CDC has recommended that two additional vaccines be routinely administered to children, thus potentially adding to the scope of injuries and deaths for which compensation may be sought from the Vaccine Trust Fund. Some economic reasoning is used to address the question of whether additional vaccines should be subject to tax and the issue of how to treat vaccines produced by State governments.

The five topics listed in Section I.A are separately addressed in the five chapters which follow. The report includes the following Appendices:

A. *Fact Sheet: Vaccine Injury Compensation Program, Post-1988 Program* and *Fact Sheet: Vaccine Injury Compensation Program, Pre-1988 Program*
B. Vaccine Injury Table
C. Schedule of Vaccinations Recommended for Children
D. *Adverse Effects of Pertussis and Rubella Vaccines* - Executive Summary
E. *Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causalty* - Executive Summary

CHAPTER 2. ESTIMATED COMPENSATION PAYMENTS

I. SUMMARY

This chapter discusses the estimation of future outlays from the Vaccine Trust Fund, presents the assumptions used to make such estimates for the President's FY 1995 budget, and compares those assumptions to VICP administrative data. The analysis concludes that the budget estimates for compensation awards in FY 1994 ($69.6 million) and FY 1995 ($54.5 million), are too high. The estimates for FY 1996 - FY 1999 ($54.5 million per year) are high based on experience to date, but are not unreasonable if cases where there is a long lag between administration of the vaccine and adjudication of the claim result in higher average awards than awards made to date. Some additional awards may result from adding Hib and hepatitis B vaccines to the Vaccine Injury Table, presuming excise taxes are enacted on these vaccines (Chapter 4).

II. FACTORS AFFECTING FUTURE COMPENSATION PAYMENTS

Future outlays from the Vaccine Trust Fund for VICP compensation awards cannot be estimated with any degree of certainty. Adverse reactions to vaccinations are rare events. Petitions for compensation are typically filed well after the vaccination was administered and judicial review of petitions is time-consuming. Even though the program of making compensation payments out of the Vaccine Trust Fund began on October 1, 1988, not enough time has elapsed to observe final resolution of all cases arising from the administration of a cohort of vaccinations.

Aggregate awards paid from the Vaccine Trust Fund, with respect to vaccinations administered during a particular year, by type of vaccine, depend upon: the number of vaccinations administered in that year; the frequency of adverse reactions; the probability that petitions will be filed following an adverse reaction;[9] the filing of petitions not in fact attributable to the adverse consequences of a vaccination; the probability that a petitioner will be awarded compensation; the size of compensation awards; the probability that attorney fees will be awarded; and the size of attorney fee awards.

The payment of awards occurs several years after the vaccination occurred. The total time lag between vaccination and payment of an award depends upon the time between vaccination and the filing of a petition, the time expended in reaching a judicial decision with respect to a petition, and the time between the decision to grant an award and payment.

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[9] Some victims of adverse reactions may be compensated through ordinary health insurance.

III. VICP OUTLAYS

Since the first cohort of Post-1988 Program cases has not been fully resolved, outlays from the Vaccine Trust Fund have not reached a "steady state" such that expected future levels would only be affected by underlying trends in the number of vaccinations administered and other factors, such as inflation and other factors determining average awards and the impact of health care reform.[10] Actual outlays from the Vaccine Trust Fund for compensation through FY 1993 (including attorney fees) are shown in Table 1[11] along with projections for FY 1994 through FY 1999. Transfers out of the Vaccine Trust Fund to other Federal government accounts to cover administrative expenses for three Federal agencies are also shown. The agencies are the Public Health Service, the Department of Justice, and the Court of Federal Claims.[12]

Outlay estimates for FY 1995 through FY 1999 were made in preparation for the FY 1995 budget by the Division of Vaccine Injury Compensation, Bureau of Health Professions, Health Resources and Services Administration in the Department of Health and Human Services. They are based on the following assumptions: 150 cases filed per year, beginning in 1994; all cases filed in one year are settled in the second following year; 78 percent of cases filed are injury cases and 22 percent death cases; 30 percent of injury claims and 48 percent of death cases ruled compensable; and average awards (including attorney fees) for injury cases are $1.5 million and $257,000 for death cases. These assumptions result in an estimated outlay of $54.4 million each fiscal year from 1995 through 1999.

Some of these assumptions can be compared with actual VICP data regarding all cases filed as of May 10, 1994, shown in Table 2. Despite the fact that the average injury award has been about $955,000, rather than the $1.5 million used to make budget forecasts, the latter amount may not be unreasonable as a long-run "steady state" estimate.[13] Average awards to date are not representative of averages in the future because VICP is not a mature program. Average awards to date are disproportionately weighted by cases adjudicated within a relatively few years of the vaccination giving rise to the claim. Cases filed later, and that take longer to adjudicate, are likely to result in higher awards.

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[10] Health insurance extended to those now uninsured would pay for some medical expenses currently included in VICP awards.

[11] All tables follow page 26.

[12] The $6 million limit on administrative expenses paid out of the Vaccine Trust Fund as provided in Section 9510(c)(1) of the Internal Revenue Code has been overridden by appropriations acts.

[13] As of May 10, 1994, 35 injury awards had been paid out of the 42 judged compensable by that date. There is typically about a two-month time lag between adjudication and payment.

The number of post-1988 cases filed declined from 191 in FY 1992 to 137 in FY 1993. If the filing of claims continues at the same pace for the entirety of FY 1994 as for the period through May 1994, 118 cases will be filed for the fiscal year as a whole. The declining number of cases filed may simply reflect a better understanding on the part of petitioners and their attorneys as to what circumstances constitute a compensable claim. In future years, compensable claims as a percentage of claims filed may therefore increase as petitions expected to be dismissed simply are not filed.

Awards for FY 1994 through that same date were on a pace that would result in a total of $23.8 million for the entire year, considerably below the budget forecast of $69.6 million. The outlay estimates for compensation contained in the FY 1995 budget for FY 1994 therefore appear to be too large. For FY 1995 the estimate of $54.5 million is also likely to be too large because the program is unlikely to have reached a steady-state in that year. The program should be mature by about FY 1996, in the sense that at least one full cohort of cases will have all been adjudicated. While compensation payments at a steady-state rate of $54.5 million per year appears high based on awards through May 1994, that level may be reached if awards for cases that take a long time to adjudicate are higher than average awards have been so far and if some additional outlays are associated with adding new vaccines to the Vaccine Injury Table (Chapter 4). Other proposed changes to the Vaccine Injury Table may also affect the steady-state level of awards. As the program matures, sufficient program data will be available to permit more sophisticated methods of estimating future outlays to be used.

Significant and growing balances in the Vaccine Trust Fund are apparent from Table 1. Excise taxes transferred to the Trust Fund each year are expected to be about twice the level of trust fund outlays.[14] Significant interest receipts also contribute to the build up of the Trust Fund balance. By the end of FY 1999, the balance in the Trust Fund is expected to be nearly 20 times as large as annual outlays. Tax rates required to maintain an adequate trust fund balance are discussed in Chapter 5.

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[14] In FY 1990 there was a catch-up transfer of excise taxes from the General Fund to the Vaccine Trust Fund to account for the excess of liabilities recorded from excise tax returns over earlier estimates of receipts which were used as a basis for transfers in 1988 and 1989. Trust fund receipts were lower than usual in 1993 because taxes on vaccines terminated on December 31, 1992 and were reenacted by OBRA '93, effective August 10, 1993. Relatively high receipts during 1994 - 1996 reflect the additional vaccines expected to be manufactured and administered in those years in order to implement the Childhood Vaccination Program. This program intends to speed up vaccinations to assure that two-year olds receive all recommended vaccinations in part by making vaccines freely available to low-income and uninsured children. Once the catch-up process is completed, vaccine production is expected to return to a steady-state level.

IV. VICP AWARDS ASSOCIATED WITH 1989 VACCINATIONS

Evidence that average awards for injury cases will eventually reach a higher level than that experienced to date may be found in the data regarding injury cases arising from vaccinations administered in 1989. About 71 million vaccines were available to be administered in 1989 (Table 3). Average injury awards for the 12 injury cases ruled compensable to date were about $1.2 million. But 104 out of 170 of these injury cases remained pending as of May 12, 1994 (Table 4), and could ultimately involve larger average compensation payments.

A total of $18.2 million had been paid out, through May 12, 1994, in VICP awards with respect to all cases arising from 1989 vaccinations (Table 5). The portion of total awards associated with each vaccine was 74.0 percent for DPT, 1.5 percent for DT, 19.4 percent for MMR, and 5.1 percent for polio. The largest average award to petitioners, $1.4 million, went to those claiming injury with respect to the DPT vaccine. The largest single award was for $3.3 million.

VICP has not matured sufficiently to estimate with confidence the dollar volume of awards that may yet be paid with respect to the undecided 55 percent of the 1989 cases. Because of the considerable time lags inherent in VICP, on average over 1000 days between vaccination and compensation payment (Table 6), the payment of awards has been spread out over the years since 1989 (Table 7).[15] Payments with respect to cases still pending may be spread out over several future years, with possibly large payments yet to come.

[15] The average of over 1053 days is for cases that have already been adjudicated. The average will increase when all pending cases associated with vaccinations in 1989 are decided.

CHAPTER 3. RATES OF INJURY AND DEATH RELATED TO VACCINATIONS

I. SUMMARY

This chapter presents data regarding VICP claims filed with respect to vaccinations administered in 1989. Based on the somewhat less than half of these claims that had been adjudicated by May 12, 1994, it appears that injuries and deaths compensable under VICP occur about once out of every one million vaccinations administered. The scientific literature indicates that most injuries and deaths of a type compensable under VICP cannot be said with certainty to have been caused by vaccines.

II. CASES ASSOCIATED WITH 1989 VACCINATIONS

Administrative records of VICP related to cases arising from vaccinations administered in 1989, the first full calendar year the Post-1988 Program was in effect, are used here, along with information taken from reports made by vaccine manufacturers to the Centers for Disease Control and Prevention (CDC), to estimate the rate at which compensable deaths and injuries occur.

There is no direct information on the number of vaccines administered in the United States each year. CDC does, however, maintain the Biologics Surveillance Reporting System which records reports made voluntarily by vaccine manufacturers of the number of net doses distributed each year.[16] These data for 1989, along with taxes paid, estimated on the basis of those amounts, are reported in Table 3. This estimate of $150.1 million in taxes paid is very close to the $151.1 million in excise tax liabilities reported on tax returns filed with the Internal Revenue Service (IRS) by manufacturers with respect to vaccines sold during calendar year 1989.[17] The IRS figure is also a net number in the sense that taxes paid on out-of-date or otherwise unusable vaccines returned to manufacturers are credited against current liabilities. The slight difference between tax liabilities reported to the IRS and estimated taxes based on CDC data may be explained by differences in timing between the two reporting systems.[18] The

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[16] The CDC data are net in the sense that vaccines returned to manufacturers are subtracted.

[17] Department of the Treasury, Internal Revenue Service, *News Release*, "Internal Revenue Report of Excise Taxes," various dates.

[18] The number of doses of specific vaccines reported to the IRS cannot be revealed here because to do so would disclose individual taxpayer information. In some cases there is only

(continued...)

CDC reports are an upper-bound estimate of the number of vaccines administered. Some unknown amount would have been discarded without being returned to the manufacturer and some net inventory accumulation may have occurred.

As an indication of how rare severe adverse reactions to vaccinations are, only 211 VICP petitions have been filed with respect to vaccinations occurring in 1989 (Table 4) out of the approximately 70 million vaccines purchased, and presumably administered, that year.[19] About 45 percent of these cases had been decided by May 12, 1994. Only 27 petitioners have been awarded compensation. If pending cases result in awards in the same proportion as decided cases, then about 60 compensation awards can be expected when all cases arising from 1989 vaccinations are finally settled. This would mean less than one award for each one million vaccines administered. Because petitioners do not have to prove that the vaccination caused the injury upon which the petition is based, so long as the injury is listed on the Vaccine Injury Table, some unknown portion of these less than one-in-a-million cases are likely to be chance occurrences rather than deaths or injuries caused by vaccinations.

III. THE SCIENTIFIC EVIDENCE

The National Childhood Vaccine Injury Act of 1986 (the 1986 Act) directed, in Section 312, that a review of scientific and other information on possible adverse consequences of pertussis (whooping cough) and rubella vaccines be conducted. The Institute of Medicine (IOM) established an 11-member interdisciplinary committee to conduct the study, the results of which

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[18](...continued)
a single producer of a particular vaccine. The difference between the $151.1 million in vaccine excise tax liabilities reported to the IRS for 1989 and the $98.7 million transferred into the Vaccine Trust Fund in FY 1989 (Table 1) is only in part due to the difference between fiscal and calendar years. Transfers to the Vaccine Trust Fund are made on a current basis based on Office of Tax Analysis estimates of taxes received and are reduced by 25 percent of expected receipts to recognize an offset for reduced income and payroll taxes (see footnote 5). Transfers are adjusted in future years for differences between those estimates and liabilities reported by the IRS. Liabilities for a particular quarter are reported with a time lag. For additional information on excise tax accounting see Bruce F. Davie, "Excise Taxes, Fiscal Year 1992" *Statistics of Income Bulletin*, Fall 1993. pp. 36-52.

[19] This data set covers cases filed through May 12, 1994. The last of these 211 cases was filed in August of 1993. It is possible that a few additional cases pertaining to 1989 vaccinations may yet be filed.

were published in 1991.[20] The committee reviewed five types of evidence: (1) human experiments; (2) animal experiments; (3) case-comparison, cohort, and other controlled studies; (4) case reports and case series; and (5) biologic plausibility.[21] Of the 22 types of adverse events studied, the evidence was judged to indicate a causal relation to vaccines with respect to three types of adverse events. The evidence was judged to be consistent with a casual relation to vaccines with respect to three other types of adverse events.[22] Partly on the basis of the findings of this committee, the Secretary of Health and Human Services (HHS) has proposed to amend the Vaccine Injury Table (see Chapter 1).

Section 313 of the 1986 Act mandated that a study be conducted of adverse events associated with vaccines commonly administered during childhood, other than pertussis and rubella vaccines. IOM created the Vaccine Safety Committee, a 14-member interdisciplinary group, to undertake this review which was published in 1994.[23] The scope of the study was expanded beyond those vaccines covered by VICP to include *haemophilus influenzae* type b (Hib) and hepatitis B vaccines because of the expectation that these vaccines would be added to the list of vaccines covered by VICP (see Chapter 4).

The Committee noted the difficulty in assessing causality when several vaccines are commonly administered at once, and when vaccines contain more than one antigen. The Committee indicated the impossibility, based on the material it reviewed, of calculating the proportion of individuals whose condition is causally related to a vaccination.[24]

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[20] Christopher P. Howson, Cynthia J. Howe, and Harvey V. Fineberg, eds., *Adverse Effects of Pertussis and Rubella Vaccines* Washington, D.C.: National Academy Press, 1991. The complete Executive Summary appears in Appendix D.

[21] *Ibid*, p.4.

[22] *Ibid*, p 7.

[23] Kathleen R. Stratton, Cynthia J. Howe, and Richard B. Johnson, Jr., eds., *Adverse Events Associated with Childhood Vaccines, Evidence Bearing on Causality* Washington, D.C.: National Academy Press, 1994. The complete Executive Summary of this study appears in Appendix E.

[24] *Ibid*, p. 17.

IV. THE VACCINE ADVERSE EVENT REPORTING SYSTEM (VAERS)

The 1986 Act required that manufacturers and health care providers who administer vaccines report serious adverse events following vaccinations to the Secretary of HHS. VAERS was created to implement this requirement, and became fully operational on November 1, 1990. VAERS is not expected to provide sufficient information to make epidemiological assessments of causality. VAERS may, however, be useful in identifying hypotheses that may be testable using other data bases.[25]

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[25] Robert T. Chen, et al, "The Vaccine Adverse Event Reporting System (VAERS)" *Vaccine*, 1994 Vol. 12, No. 6, pp. 542-50.

CHAPTER 4. NEW VACCINES AND IMMUNIZATION PRACTICES THAT MAY BE COVERED BY VICP

I. SUMMARY

The Secretary of Health and Human Services (HHS) is expected to exercise authority granted by OBRA '93 to add hepatitis B and Hib vaccines to the Vaccine Injury Table. Following that action, enactment of taxes on these vaccines will expand VICP to cover vaccinations using them. Some additional petitions for compensation under VICP will probably be filed and compensation payments made as a result.

II. RECOMMENDATIONS OF THE CENTERS FOR DISEASE CONTROL AND PREVENTION

The Centers for Disease Control and Prevention (CDC), through the Advisory Committee on Immunization Practices, recommended prior to August 1, 1993, that two additional vaccines be routinely administered to children. These two vaccines are the *Haemophilus influenzae* type b (Hib) and hepatitis B vaccines.[26] The Secretary of HHS is required by OBRA '93 to revise the Vaccine Injury Table by August 1, 1995, to include these vaccines in the Table. Recipients of these vaccines will not be covered by VICP , however, until excise taxes are in place for these vaccines. Neither the Secretary of HHS nor the Secretary of the Treasury has the authority to impose any tax on manufacturers of these vaccines when they are included in VICP by virtue of their addition to the Vaccine Injury Table.

III. DE FACTO VICP COVERAGE OF UNTAXED VACCINES

Vaccinations are commonly administered at the same time using several different vaccines. So long as one of the vaccines being administered, whether to children or adults, is subject to excise tax and is listed on the Vaccine Injury Table, an adverse reaction covered by the table can be compensated under VICP, even if the reaction is to a vaccine not covered by the table. A VICP petitioner need not prove that the adverse event was caused by a currently covered vaccine, rather than by another vaccine administered at the same time.

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[26] The children's vaccination schedule currently recommended by the American Academy of Pediatrics and CDC's Advisory Committee on Immunization Practices appears in Appendix C.

IV. CONSEQUENCES FOR THE VACCINE TRUST FUND

Some additional outlays from the Vaccine Trust Fund may be caused by the addition of Hib and hepatitis B vaccines to the Vaccine Injury Table, presuming taxes are enacted on these vaccines. The effect is not expected to be major, however, because many children already receive these vaccines at the same time they receive other vaccines. In these cases, adverse events, such as anaphylaxis, are already covered in connection with the other vaccines. Other conditions may be added to the Vaccine Injury Table for these vaccines as a result of mandated rulemaking. Furthermore, petitioners may receive compensation for a condition not listed on the Table, if they can prove that the vaccine caused that condition. Adults to whom Hib and hepatitis B vaccines are administered would be covered, but are less likely to receive vaccines currently covered by the Vaccine Injury Table at the same time. Additional outlays from the Vaccine Trust Fund as a result of including these two vaccines on the Vaccine Injury Table are thus likely to be related primarily to petitions filed on behalf of adults.

CHAPTER 5. INCLUDING ADDITIONAL VACCINES IN VICP

I. SUMMARY

A strong economic rationale exists for taxing vaccines to cover the costs of compensating those adversely affected by vaccinations, so long as compensation is to be paid out of public funds. Taxes on individual vaccines have been set in an attempt to relate them to the expected compensation payments associated with each covered vaccine. On the basis of this rationale, present law tax rates may need to be adjusted and *Haemophilus influenzae* type b (Hib) and hepatitis B vaccines should be added to the list of taxed vaccines when these two vaccines are added to the Vaccine Injury Table. Changes in vaccine technology, pending revisions to the Table, and other factors suggest that Congress may need to consider shifting away from risk-related taxation to a flat tax on each antigen contained in vaccines.

II. THE RATIONALE FOR TAXING VACCINES

A. The Cost of Vaccinations

The manufacture of vaccines involves certain labor, capital and raw material costs, like the production of any other commodity. The capital costs include the costs of research and development necessary to bring a vaccine into production and meet the requirements of regulatory agencies seeking to assure that the vaccine is safe and effective. In addition, administering vaccines incurs costs for the labor services of doctors and nurses and some capital costs. In the United States, the costs of manufacturing vaccines have traditionally been incurred by private drug companies who sell vaccines to the private physicians, health maintenance organizations, and public agencies who administer vaccinations.

There is another cost of vaccinations, beyond the costs of manufacturing and administering vaccines. This is the cost of adverse events. These adverse events are rare, and difficult to associate causally with particular vaccines or antigens when several are administered at the same time. When they do occur, adverse events associated with vaccinations can result in death and impose significant medical and personal care costs on the individuals and families involved, in addition to emotional burdens.

There are three ways in which the costs of adverse events associated with vaccinations are accommodated. First, individuals receiving vaccinations could bear the risk of incurring the costs associated with adverse events. Health insurance, or other forms of insurance, would be used by some individuals to protect against incurring such costs directly. In the absence of universal health insurance, others would not be insured against such risks, or only partially

insured. Insurance would be unlikely to cover some of the costs, such as long term care, pain and suffering, and death.

A second approach is for vaccine manufacturers to pay the costs of adverse events. The difficulty of proving manufacturer negligence under traditional tort law, plus the understandable tendency of juries to award huge settlements when confronted with a severely damaged child, was regarded by the Congress as an unsatisfactory method of covering these costs when VICP was established in 1986.

The third approach is to use public funds to compensate the individuals who directly bear the costs of adverse events associated with vaccinations. The strong public interest served by widespread vaccination practices, as implemented by requirements that children be vaccinated before entering school, is a reason for treating the costs of these adverse events as eligible for compensation from public funds.[27] Vaccinations protect not only those who are vaccinated, but reduce the risk that others contract diseases. Over the years, publicly supported vaccination programs have eliminated smallpox and virtually eliminated polio. As further examples, diphtheria cases have been reduced from about 207,000 in 1921 to 2 in 1993, pertussis from 265,000 in 1943 to about 6,000 in 1993, and rubella from about 58,000 in 1969 to 188 in 1993.[28] Protecting the very few who endure adverse events from vaccinations can benefit the many, because protection can be expected to encourage participation in vaccination programs.

Current practice in the United States is to use a combination of all three approaches to covering the costs of adverse vaccination events. For some persons, ordinary health insurance covers the cost. VICP is available to those experiencing events covered by the Vaccine Injury Table or who can prove that a covered vaccine was responsible for the adverse event. Individuals may also seek relief through the tort law if they reject the decision rendered with respect to a VICP petition.

B. Appropriate Tax Rates

The reason to finance public compensation for victims of adverse vaccination events out

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[27] Vaccinations against rubella and hepatitis B are also required for many health care workers. Any adverse event suffered by one of these adults with respect to a rubella vaccination is already covered by VICP because these vaccinations are currently covered by the Vaccine Injury Table and are subject to excise tax. Because vaccination with a hepatitis B vaccine is now recommended for children, those adults for whom these vaccinations are required (and others as well) will also be covered when the Vaccine Injury Table is amended to include hepatitis B and Hib vaccines and the excise tax is extended to these vaccines.

[28] Chen et al (1994), *op. cit.*, p. 543.

of funds derived from excise taxes on vaccine manufacturers, rather than general revenues, is to assure that the cost of vaccines reflects not only manufacturing costs, but the costs of adverse events as well.[29] The costs of adverse events are as much a cost of vaccinations as the costs of raw materials. If tort law were the primary means of assuring compensation payments for adverse events, then these costs would also be reflected in the prices charged by those who produce and administer vaccines.

The principle of using excise taxes to cover the cost of adverse vaccination-related events paid for out of public funds could be implemented in one of two ways. The first, which Congress followed in creating the Vaccine Trust Fund, is to tax individual vaccines in proportion to the costs of the adverse events with which they are individually associated. The second, discussed in the next section, is to impose a tax on all covered vaccines at a flat rate.

There is a major advantage to the approach of having the costs of compensating for adverse events reflected in vaccine prices. If the prices of particular vaccines reflect the costs of compensating for the adverse events associated with them, then these prices act as a signaling device, directing research and development activities to the search for new vaccines that reduce the risk of adverse events.

There are several disadvantages associated with this risk-related approach to setting excise tax rates. The relative risks associated with specific vaccines are likely to change over time as new forms of vaccines (such as the acellular pertussis vaccine recently introduced and approved by the Food and Drug Administration for use in the fourth and fifth series of childhood DPT inoculations) that are expected to reduce the incidence of adverse events come into use. As more antigens are bundled into single vaccinations, it becomes increasingly difficult to attribute adverse events to any particular antigen. Changes in the recommended schedule of vaccinations will also change these relative risks. Changing the specifics of the Vaccine Injury Table will also change the relative costs of compensation awards associated with different vaccines. Finally, as new vaccines are added to the list of those recommended for children, accurate information on the costs of adverse events associated with those vaccines is likely to be unavailable. New vaccines may be proven to be completely acceptable on the basis of clinical trials involving thousands of doses, yet a few adverse events may occur once they are administered routinely to millions of children.

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[29] Theoretically, the principle of internalizing the costs of adverse events into the price of vaccinations could be achieved by imposing a tax on the administration of vaccinations rather than the manufacture of vaccines. As a practical matter, however, taxing a few manufacturers is vastly easier, as an administrative matter, and minimizes both private and public compliance costs than would taxing thousands of persons who administer vaccinations.

Present law tax rates were set with the expectation that the relative amounts of revenue from the separately taxed vaccines would be in the following proportions, expressed in percentage terms:

DPT	76.98
DT	0.05
MMR	18.75
Polio	4.22

These proportions took into account the number of vaccines recommended for children and reflected "...currently accepted views regarding the relative reactogenicty of vaccines."[30] They can be compared to the percentage distribution of VICP awards arising from 1989 vaccinations, through May 12, 1994, derived from the data in Table 5, and with the percentage distribution of estimated 1989 tax receipts, by vaccine (based on data reported to CDC as shown in Table 3).

	Awards	Revenues
DPT	74.0	66.5
DT	1.5	0.8
MMR	19.4	29.0
Polio	5.1	3.7

Comparing the percentage distributions of awards and revenues suggests that the tax rate on DPT vaccines is somewhat too low and the rate on MMR vaccines is somewhat too high, in relative terms. The relative distribution of VICP awards for 1989 may, of course, change when all pending cases have been adjudicated. If the risk-related approach to setting excise tax rates is to be maintained, relative tax rates may need to be altered so that the distribution of receipts as among different vaccines better matches the distribution of awards. Making such a change should wait until the adjustment can be based on at least a few cohorts of cases arising from vaccinations in a given year that have been fully adjudicated.

Setting relative tax rates on vaccines is only half the job required to determine appropriate tax rates on vaccines. Rates should also be set, in terms of absolute amounts per dose, at levels that will generate an appropriate amount of Vaccine Trust Fund receipts. To date, excise taxes transferred to the Vaccine Trust Fund have exceeded trust fund outlays in every year (Table 1). As a consequence, the trust fund has been accumulating a growing surplus. The surplus is invested in Treasury securities and interest earnings on those securities

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[30] H.R. Rept. 99-908, September 26, 1986, p. 34. Congressional deliberations regarding relative tax rates occurred in conjunction with the 1986 Act even though the taxes were not enacted until OBRA '87.

are also deposited into the trust fund. By the end of FY 1999 the balance in the Vaccine Trust Fund is expected to reach $1.2 billion. Some positive trust fund balance is appropriate to assure that compensation payments can be made should there be an unusual outbreak of adverse events leading to an increase in compensation awards. A balance equal to three times steady-state annual outlays, or about $200 million, should be sufficient for such a precautionary purpose.[31] Reducing the absolute levels of tax rates would be necessary to prevent any additional increase in the ratio of fund balances to annual outlays.

C. Tax Rate Recommendation of the Advisory Commission on Childhood Vaccines

The second approach to setting excise tax rates is to impose a flat tax on all vaccines, or all antigens, so as to generate the desired aggregate amount of revenue. The Advisory Commission on Childhood Vaccines has recommended to the Secretary of Health and Human Services (HHS) that a flat rate of $.50 per dose be applied to all vaccines covered by the Vaccine Injury Table.[32] The Commission intends that the tax be applied on a per antigen basis so that, for example, DPT and MMR would each be taxed at a rate of $1.50 per dose.[33] The major advantage of the Commission's recommendation is that it addressed concerns that epidemiological evidence was becoming increasingly uncertain with respect to the association of adverse events with particular antigens. They were advised that changing vaccine technology, changes to the Table, and other factors would make the problem of determining such associations even more difficult in the future. Another purpose of the recommendation was to address the concern that taxes on vaccines were too high relative to VICP outlays. Reducing vaccine taxes in the aggregate is consistent with the goal of adequately funding the Vaccine Trust Fund, given the current and projected fund balances.

The disadvantage of a flat-rate approach to setting excise tax rates is that it forecloses the ability to relate excise taxes on specific vaccines to the level of compensation payments related to those vaccines. Even if petitioners need not prove that their adverse event was caused by a vaccine when the event falls within the terms of the Vaccine Injury Table, it still will be the case that compensation payments are disproportionately related to some vaccines rather than others.

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[31] The Advisory Commission on Childhood Vaccines (ACCV), created by the National Childhood Vaccine Injury Act of 1986, has recommended that the Vaccine Trust Fund balance be maintained at a level equal to three years' of awards. (Letter from Gerald M. Fenichel, M.D. Chairman, ACCV to The Honorable Donna E. Shalala, Secretary, Department of Health and Human Services, December 14, 1993.)

[32] The Secretary of HHS has not endorsed this recommendation.

[33] *Ibid.* This feature of the Commission's recommendation, that vaccines be taxed on a per antigen basis, is appropriate whether tax rates are set on a risk-related basis or on a flat rate basis.

III. TAXING ADDITIONAL VACCINES

As indicated in Chapter 4, two additional vaccines, Hib and hepatitis B, are expected to be added to the Vaccine Injury Table by the Secretary of HHS. It is recommended that after this occurs, Section 4131 of the Internal Revenue Code be amended to add these two vaccines to the list of taxable vaccines so that related adverse events are covered by VICP. Because sufficient information is not available to assess the probable future costs associated with compensating expected adverse events associated with these vaccines and the new provisions of the Table, a flat rate tax should be considered. The Advisory Commission on Childhood Vaccines has recommended a rate of $.50 per vaccine. Another option is to set the rate equal to the lowest tax rate on any other vaccine.

If other vaccines are subsequently added to the Vaccine Injury Table by administrative action of the Secretary of Health and Human Services, Section 4131 of the Code should be similarly amended. As an alternative method of accommodating new vaccines approved for public use by the Food and Drug Administration and recommended for routine administration to children by CDC's Advisory Committee on Immunization Practices, the Code could be amended to establish an excise tax, at a preset rate, triggered by the formal recommendation of the Committee or the inclusion of the vaccine in the Vaccine Injury Table. The tax rate could be adjusted by subsequent legislative action to comport with actual experience regarding compensation awards related to a new vaccine.

CHAPTER 6. TAXING VACCINES PRODUCED BY STATE AGENCIES

I. SUMMARY

Two States, Massachusetts and Michigan, manufacture vaccines to supply publicly-supported vaccination programs. A 1988 technical amendment to Section 4132 of the Internal Revenue Code[34] made it clear that vaccines manufactured by States are to be taxed.[35] Taxing these vaccines is consistent with the rationale for funding VICP with revenue from excise taxes, even though there is also a rationale for public provision of vaccinations.

II. THE RATIONALE FOR TAXING VACCINES PRODUCED BY STATES

VICP covers adverse events associated with vaccinations using vaccines produced by States as well as those produced by private drug companies. The cost of compensating those who suffer adverse events associated with vaccinations using State-produced vaccines are a part of the total cost of those vaccinations. The rationale for taxing vaccinations outlined in Section II of Chapter 5 applies equally to State-produced vaccines and privately-produced vaccines. If State-produced vaccines were untaxed, those vaccines would appear to be artificially cheaper than privately-produced vaccines. States maintaining extensive free or low-cost vaccination programs might thereby be encouraged to produce their own vaccines even though actual production costs might be higher, due to economies of scale, than production costs for private firms.

III. THE RATIONALE FOR PUBLIC PROVISION OF VACCINATIONS

Vaccinations benefit the public at large by limiting or preventing the spread of certain diseases. Young children, if not vaccinated, are particularly susceptible to the diseases for which vaccines have been developed and which are covered by VICP. Despite evidence that the risk of adverse events is extremely low, and despite covering those risks through VICP, many

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[34] Technical and Miscellaneous Revenue Act of 1988 (P.L. 100-647), Section 2006.

[35] If a State produces vaccines and uses them in a "free" vaccination program, there is no sale of the vaccine. The 1988 amendment made it clear that the taxable event in this case was the use of the vaccine. This follows general excise tax principles that taxable articles used by their manufacturer are taxed. For example, gasoline used by a refiner to fuel its own trucks is taxable even though it is never sold.

children in the United States are not vaccinated at recommended times. For example, the Centers for Disease Control and Prevention (CDC) reported that, for 1991, only 37.2 percent of two year olds and 42.1 percent of one to four year olds were up to date on vaccinations.[36] Cost may be a factor explaining these low vaccination rates. The tax-included 1993 catalogue price to those who administer vaccinations privately of the full series of vaccines recommended for children (including Hib and hepatitis B vaccines) was $252. The tax component of the price was $32.84.[37] To address the concern that vaccine prices discourage immunization, a recently enacted Federal program will, in FY 1995, purchase $425 million of vaccines for low-income and uninsured children and provide them to these children free of charge.[38]

CDC anticipates that nearly 55 million doses of vaccines currently covered by VICP will be purchased by State and Federal agencies during FY 1995. If public purchases occur at this level, the major part of total Vaccine Trust Fund receipts for FY 1995 will come out of State and Federal budgets. To exempt these public purchases from vaccine excise taxes would be inappropriate. If there were such an exemption, public entities would not be paying for the full cost of the vaccination programs they support. The cost of adverse events associated with those vaccinations would go uncovered. There is nothing inconsistent with publicly providing or subsidizing vaccinations and at the same time taxing vaccines purchased or produced with government outlays as a means of funding VICP.

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[36] *Statistical Abstract of the United States, 1993*, p. 133.

[37] Data supplied by VICP staff.

[38] The VICP staff report that the 1993 contract price to the Federal government for the full series of childhood vaccines was $111 per child, including the tax component of $32.84.

Table 1

VACCINE INJURY COMPENSATION TRUST FUND, FISCAL YEARS 1988 – 1999
(thousands of dollars)

Fiscal Year	Opening Balance	Excise Tax Receipts	Interest Received	Appropriations: Compensation Payments	Appropriations: Administrative Costs	Ending Balance
1988	0	74,038	580	0	0	77,547
1989	77,547	98,719	10,857	0	0	190,930
1990	190,300	158,551	21,600	261	2,844	368,560
1991	368,560	80,884	29,158	4,200	4,928	476,000
1992	476,000	117,788	28,381	13,022	6,811	602,336
1993	601,564	37,868 *	25,957	14,993	7,169	643,227
1994 est.	643,227	147,605	19,200	69,611	7,160	733,261
1995 est.	733,261	140,576	21,900	54,476	8,250	833,011
1996 est.	833,011	140,576	24,900	54,476	8,250	933,516
1997 est.	933,516	121,642 **	27,900	54,476	8,250	1,018,087
1998 est.	1,018,087	121,642	30,400	54,476	8,250	1,105,158
1999 est.	1,105,158	121,642	33,100	54,476	8,250	1,194,929

Department of the Treasury
Office of Tax Analysis

* Reflects termination of taxes on December 31, 1992 and reenactment of taxes effective August 10, 1993.

** Reflects assumed success of program to assure timely vaccinations of all children by age two (see text).

Note: Opening balances plus receipts and minus appropriations do not necessarily equal ending balances because of changed trust fund accounting concepts.

Source: Budget of the United States Government, Appendix, various years and VICP forecast.

Table 2

DISPOSITION OF VICP CASES ARISING FROM
VACCINATIONS ADMINISTERED AFTER SEPTEMBER 30, 1988
(through May 10, 1994)

Vaccine/ Death or Injury	Cases Filed	Cases Dismissed	Cases Adjudicated		Compensation Paid	Cases Pending	Awards* (thousands of dollars)
			Compensable	Not Compensable			
DPT – Death	96	19	30	4	29	43	7,337
DPT – Injury	226	35	30	12	25	149	27,640
DT – Death	3	2	1	0	1	0	273
DT – Injury	24	4	1	1	1	18	67
MMR – Death	11	0	2	3	2	6	512
MMR – Injury	128	23	6	1	5	98	3,719
Polio – Death	5	1	3	0	2	1	521
Polio – Injury	28	4	5	0	4	19	1,980
TOTAL	521	88	78	21	69	334	42,049
Death	115	22	36	7	34	50	8,643
Injury	406	66	42	14	35	284	33,406

Department of the Treasury
Office of Tax Analysis

* Only cases where compensation paid to petitioners.

Source: VICP administrative data.

Table 3

NET DOSES OF VACCINES AVAILABLE AND ESTIMATED TAXES, CALENDAR YEAR 1989*

Vaccine	Net Doses Available (millions)	Tax Rate	Estimated Taxes (millions of dollars)	Percentage of Total Implicit Taxes
DPT	22.0	$4.56	$100.1	66.5
DT	20.3	$0.06	$1.2	0.8
MMR	9.8	$4.44	$43.6	29.0
Polio	19.1	$0.29	$5.5	3.7
TOTAL	71.1		$150.1	100.0

Department of the Treasury
Office of Tax Analysis

* "Implicit taxes" are net doses available times tax rates and are not equal to tax liabilities reported to the Internal Revenue Service (see text).

Note: Detail may not add to totals due to rounding.

Source: Centers for Disease Control and Prevention, Biologics Surveilance Reporting System.

Table 4

DISPOSITION OF VICP CASES ARISING FROM 1989 VACCINATIONS
(through May 12, 1994)

Vaccine/ Death or Injury	Cases Filed	Cases Decided	Compensation Awards	Attorney Fees Awarded Only	Cases Pending
DPT – Death	36	25	13	3	11
DPT – Injury	95	43	7	15	52
DT – Death	2	2	1	0	0
DT – Injury	6	2	0	1	4
MMR – Death	1	1	0	0	0
MMR – Injury	57	17	3	10	40
Polio – Death	2	1	1	0	1
Polio – Injury	12	4	2	1	8
TOTAL	211	95	27	30	116
Death	41	29	15	3	12
Injury	170	66	12	27	104

Department of the Treasury
Office of Tax Analysis

Source: VICP administrative data.

Table 5

PAYMENTS FOR VICP CASES ARISING FROM 1989 VACCINATIONS
(through May 12, 1994)

Vaccine/ Death or Injury	Total Payments			Average Payments		
	Awards to Petitioners	Attorney Fees	Total	Award to Petitioners	Attorney Fees	Total Award*
DPT – Death	$2,935,000	$279,985	$3,214,985	$225,769	$17,499	$246,039
DPT – Injury	$9,962,693	$278,946	$10,241,639	$1,423,242	$12,679	$1,446,079
DT – Death	$250,000	$22,940	$272,940	$250,000	$22,940	$272,940
DT – Injury	$0	$2,978	$2,978	$0	$2,978	$0
MMR – Death	$0	$0	$0	$0	$0	$0
MMR – Injury	$3,221,109	$304,169	$3,525,278	$1,073,703	$23,398	$1,099,173
Polio – Death	$250,000	$3,279	$253,279	$250,000	$3,279	$253,279
Polio – Injury	$626,562	$42,606	$669,168	$313,281	$14,202	$332,328
TOTAL	$17,245,364	$934,903	$18,180,267	$638,717	$16,402	$659,610
Death	$3,435,000	$306,204	$3,741,204	$229,000	$17,011	$248,315
Injury	$13,810,364	$628,699	$14,439,063	$1,150,864	$8,428	$1,173,727

Department of the Treasury
Office of Tax Analysis

* Excludes cases where payments of attorney fees were made but no award was made to petitioner.

Source: VICP administrative data.

Table 6

AVERAGE TIME BETWEEN VACCINATION AND PAYMENT
FOR VICP CASES ARISING FROM 1989 VACCINATIONS
(through May 12, 1994)

Vaccine/ Death or Injury	Average Number of Days Between: Vaccination and Filing	Filing and Judgment	Judgment and Payment*	Vaccination and Payment*
DPT – Death	676	481	56	1,048
DPT – Injury	865	701	88	1,296
DT – Death	789	558	68	1,293
DT – Injury	911	311	na	na
MMR – Death	811	373	na	na
MMR – Injury	943	683	53	1,402
Polio – Death	958	346	60	1,506
Polio – Injury	865	465	27	995
AVERAGE	855	543	63	1,053

Department of the Treasury
Office of Tax Analysis

* Excludes cases where only attorney fees were awarded.

na = not applicable (no compensation awarded in these cases)

Table 7

VICP COMPENSATION PAYMENTS, BY YEAR:
CASES ARISING FROM 1989 VACCINATIONS

Calendar year	Compensation payments:*		
	Number	Amount	Average
1990	1	$261,247	$261,247
1991	7	$3,019,210	$431,316
1992	8	$3,334,327	$416,791
1993	9	$10,645,141	$1,182,793
1994**	2	$549,531	$274,766
TOTAL	27	$17,809,457	$659,610

Department of the Treasury
Office of Tax Analysis

* Excludes cases where only attorney fees were awarded.

** Through May 12.

Source: VICP administrative data.

APPENDIX A

Fact Sheet: Vaccine Injury Compensation Program, Post-1988 Program
and
Fact Sheet: Vaccine Injury Compensation Program, Pre-1988 Program

HEALTH RESOURCES AND SERVICES ADMINISTRATION

FACT SHEET

OFFICE OF COMMUNICATIONS • PROGRAM SERIES • SEPTEMBER 1993

VACCINE INJURY COMPENSATION PROGRAM

POST-1988 PROGRAM

Program Description

The Vaccine Injury Compensation Program (VICP) is a no-fault alternative to the tort system for resolving claims resulting from adverse reactions to covered vaccines. Vaccines covered by the Act include diphtheria, tetanus, pertussis (DTP, DT, TT, or Td); measles, mumps, rubella (MMR or any components); and polio (OPV or IPV). The VICP is administered jointly by the United States Court of Federal Claims (the Court), the Department of Health and Human Services (HHS), and the Department of Justice (DOJ). An individual claiming injury or death from a vaccine files a petition for compensation with the Court. A physician at the Division of Vaccine Injury Compensation, HHS, reviews each petition to determine whether it meets the criteria for compensation and makes a recommendation in the form of a respondent's report that is filed with the Court by DOJ.

There are two means to qualify for compensation: (1) a petitioner must prove that the vaccine caused the injury, or (2) a petitioner must prove that an injury listed on the Vaccine Injury Table, as set forth in the Act, occurred within the specified time periods.

The Act distinguishes in terms of the date of vaccination, the elements of compensation, source of funds, and court processing time between vaccines administered **prior to** October 1, 1988 (pre-1988 claims), and those administered **on or after** this date (post-1988 claims). This fact sheet provides general information relevant to all claims and specific information on post-1988 claims.

Filing Claims

For post-1988 claims involving an injury, the effects must have continued for at least 6 months after vaccine administration and the claim must be filed within 36 months after the first symptom appeared. For post-1988 claims involving a death, the claim must be filed within 24 months of the death and within 48 months after the onset of the vaccine-related injury from which the death occurred.

Elements of Compensation for Post-1988 Claims

For death-related claims, the total benefit allowed by law is $250,000. In injury claims, the amount of compensation is determined by the Court based on the needs of the individual and the extent of the injury. The award may include past and future non-reimbursable medical, residential, custodial and rehabilitation expenses not otherwise covered by a third-party payor. In addition, an amount may be awarded for lost earnings, pain and suffering, and reasonable attorneys' fees and costs.

Adjudication

Petitions for compensation are adjudicated by the Court, and the Secretary of HHS is named as the respondent. Attorneys from DOJ represent HHS in hearings before a "Special Master", appointed by the Court, who makes the initial decision on the petition for compensation. Either party may file an objection to the decision of a Special Master and request review by the Court. Appeals of judgments by the Court are heard by the Federal Circuit Court of Appeals.

The responsibility for determining the order in which petitions will be heard lies with the Court. The Court has indicated that the processing order for each claim depends on issues germane to each specific claim, e.g., adequacy of medical documentation, type of vaccine involved, etc. For additional information pertaining to how claims are scheduled to be heard, an individual

FACT SHEET

may write to the Clerk of the United States Court of Federal Claims, 717 Madison Place, N.W., Washington, D.C. 20005, or call (202) 219-9657.

The Court has approximately 14 months from the date a petition is filed to render a decision on post-1988 claims, counting all available suspension time. After the deadline has passed, the Court may retain jurisdiction over a petition with the consent of the petitioners.

Payment of Awards

For post-1988 claims, awards are paid from the Vaccine Injury Compensation Trust Fund, which is funded by an excise tax on covered vaccines as follows: DPT, or any Pertussis containing combination - $4.56; DT, D or T - $0.06; MMR, MM, MR, M, or R - $4.44; and Polio - $0.29.

Status of Funds

Based on awards thus far for post-1988 claims, the amount of funds available is sufficient.

Advisory Commission on Childhood Vaccines

The ACCV meets quarterly and is composed of nine appointed voting members -three health professionals, three members of the general public and three attorneys and four ex-officio members. The ACCV advises the Secretary on implementation of the compensation program and recommends changes in the vaccine injury table.

Additional Information

For more information about the Program, write the National Vaccine Injury Compensation Program, Health Resources and Services Administration, Parklawn Building, Room 8-05, 5600 Fishers Lane, Rockville, Maryland 20857; or call 301-443-6593. For specific information on how to file a claim call: 1-800-338-2382 toll free.

For more information, contact the Office of Communications, HRSA, 5600 Fishers Lane, Room 14-43, Rockville, Maryland 20857, or telephone (301) 443-3376 / fax (301) 443-1989

HEALTH RESOURCES AND SERVICES ADMINISTRATION

FACT SHEET

OFFICE OF COMMUNICATIONS • PROGRAM SERIES • SEPTEMBER 1993

VACCINE INJURY COMPENSATION PROGRAM

PRE-1988 PROGRAM

(Legislative Deadline for Filing Claims Expired January 31, 1991)

Program Description

The Vaccine Injury Compensation Program (VICP) is a no-fault alternative to the tort system for resolving claims resulting from adverse reactions to covered vaccines. Vaccines covered by the Act include diphtheria, tetanus, pertussis (DTP, DT, TT, or Td); measles, mumps, rubella (MMR or any components); and polio (OPV or IPV). The VICP is administered jointly by the United States Court of Federal Claims (the Court), the Department of Health and Human Services (HHS), and the Department of Justice (DOJ). An individual claiming injury or death from a vaccine files a petition for compensation with the Court. A physician at the Division of Vaccine Injury Compensation, HHS, reviews each petition to determine whether it meets the criteria for compensation and makes a recommendation in the form of a respondent's report that is filed with the Court by DOJ.

There are two means to qualify for compensation: (1) a petitioner must prove that the vaccine caused the injury, or (2) a petitioner must prove that an injury listed on the Vaccine Injury Table, as set forth in the Act, occurred within the specified time periods.

The Act distinguishes in terms of the date of vaccination, the elements of compensation, source of funds, and court processing time between vaccines administered **prior to** October 1, 1988 (pre-1988 claims), and those administered **on or after** this date (post-1988 claims). The deadline for filing pre-1988 claims under the program expired on **January 31, 1991**. This fact sheet provides general information relevant to all claims and specific information on pre-1988 claims.

Elements of Compensation for Pre-1988 Claims

For death-related claims, the total benefit allowed by law is $250,000. In injury claims, the amount of compensation is determined by the Court based on the needs of the individual and the extent of the injury. The award may include future non-reimbursable medical, residential, custodial and rehabilitation expenses not otherwise covered by a third-party payor. In addition, up to a total of $30,000 for pre-1988 claims may be awarded for lost earnings, pain and suffering, and reasonable attorneys' fees and costs.

Adjudication

Petitions for compensation are adjudicated by the Court, and the Secretary of HHS is named as the respondent. Attorneys from DOJ represent HHS in hearings before a "Special Master", appointed by the Court, who makes the initial decision on the petition for compensation. Either party may file an objection to the decision of a Special Master and request review by the Court. Appeals of judgments by the Court are heard by the Federal Circuit Court of Appeals.

The responsibility for determining the order in which petitions will be heard lies with the Court. The Court is now seeking input from HHS on whether cases are sufficiently documented to proceed to full review; the intial review is based on the assignment of cases by the Court, generally in the order received by the Court, as reflected by the Court's docket numbers. For additional information pertaining to how claims are scheduled to be heard, an individual may write to the Clerk of the United States Court of Federal Claims, 717 Madison Place, N.W., Washington, D.C. 20005, or call (202) 219-9657.

The Court has approximately 44 months from the date a petition is filed to render a decision on pre-1988 claims, including all available suspension time. After the deadline has passed, the Court may retain jurisdiction over a petition with the consent of the petitioners.

FACT SHEET

Payment of Awards

For pre-1988 claims, awards are paid from general fund appropriations authorized by the Congress at $110 million per year. HHS pays awards for pre-1988 claims based on the order in which the Court resolves claims.

Advisory Commission on Childhood Vaccines

The ACCV meets quarterly and is composed of nine appointed voting members--three health professionals, three members of the general public and three attorneys and four ex-officio members. The ACCV advises the Secretary on implementation of the compensation program and recommends changes in the vaccine injury table.

Additional Information

For more information about the Program, write the National Vaccine Injury Compensation Program, Health Resources and Services Administration, Parklawn Building, Room 8-05, 5600 Fishers Lane, Rockville, Maryland 20857; or call 301-443-6593. For specific information on how to file a claim call: 1-800-338-2382 toll free.

For more information, contact the Office of Communications, HRSA, 5600 Fishers Lane, Room 14-43, Rockville, Maryland 20857, or telephone (301) 443-3376 / fax (301) 443-1989

APPENDIX B

Vaccine Injury Table

TABLE 1: VACCINE INJURY TABLE

ILLNESS, DISABILITY, INJURY OR CONDITION COVERED*	TIME PERIOD FOR FIRST SYMPTOM OR MANIFESTATION OF ONSET OR OF SIGNIFICANT AGGRAVATION AFTER VACCINE ADMINISTRATION
I. DTP; P; DT; Td; or Tetanus Toxoid; or in any combination with Polio; or any Other Vaccine Containing Whole Cell Pertussis Bacteria, or Partial Cell Pertussis Bacteria, or Specific Pertussis Antigen(s)	
A. Anaphylaxis or anaphylactic shock.	24 hours
B. Encephalopathy (or encephalitis)	3 days
C. Shock-collapse or hypotonic or hyporesponsive collapse	3 days
D. Residual seizure disorder as defined below**.	3 days
II. Measles, mumps, rubella, or any vaccine containing any of the foregoing as a component;	
A. Anaphylaxis or anaphylactic shock.	24 hours
B. Encephalopathy (or encephalitis)	15 days (for mumps, rubella, measles, or any vaccine containing any of the foregoing as a component) 3 days (for DT, Td, or tetanus toxoid)
C. Residual seizure disorder as defined below**.	same as for encephalopathy
III. Polio Vaccines (other than Inactivated Polio Vaccine)	
A. Paralytic Polio	
--- in a non-immunodeficient recipient.	.30 days
--- in an immunodeficient recipient.	.6 months
--- in a vaccine associated community case	.Not applicable
IV. Inactivated Polio Vaccine	
A. Anaphylaxis or anaphylactic shock.	24 hours

* For any covered vaccine the following applies: Any acute complication or sequela including death) of an illness, disability, injury or condition referred to above that arose within the time period prescribed is also subject to the presumption of causation.

** A petitioner may be considered to have suffered a residual seizure disorder if the petitioner did not suffer a seizure or convulsion unaccompanied by fever or accompanied by a fever of less than 102 degrees F before the first seizure or convulsion after the administration of the vaccine involved and if:

(a) in the case of measles, mumps, or rubella vaccine or any combination of such vaccines, the first seizure or convulsion occurred within 15 days after administration of the vaccine and two or more seizures or convulsions occurred within one year after the administration of the vaccine which were unaccompanied by fever or accompanied by a fever of less than 102 degrees F. and;

(b) in the case of any other vaccine, the first seizure or convulsion occurred within three days after the administration of the vaccine and two or more seizures or convulsions occurred within one year after the administration of the vaccine which were unaccompanied by a fever or accompanied by a fever of less than 102 degrees F.

APPENDIX C

Schedule of Vaccinations Recommended for Children

Recommended schedule for active immunization of normal infants and children*

Recommended age†	Vaccine(s)§	Comments
2 mos	DTP#1¶, OPV#1**	OPV and DTP can be given earlier in areas of high endemicity
4 mos	DTP#2, OPV#2	6-wk to 2-mo interval desired between OPV doses
6 mos	DTP#3	An additional dose of OPV at this time is optional in areas with a high risk of poliovirus exposure
15 mos††	MMR§§, DTP#4, OPV#3	Completion of primary series of DTP and OPV
18 mos	HbCV¶¶	Conjugate preferred over polysaccharide vaccine***
4–6 yrs	DTP#5†††, OPV#4	At or before school entry
14–16 yrs	Td§§§	Repeat every 10 yrs throughout life

*See Table 3 for the recommended immunization schedules for infants and children up to their seventh birthday not immunized at the recommended times.

†These recommended ages should not be construed as absolute, e.g., 2 months can be 6–10 weeks. However, MMR should not be given to children <12 months of age. If exposure to measles disease is considered likely, then children 6 through 11 months old may be immunized with single-antigen measles vaccine. These children should be reimmunized with MMR when they are approximately 15 months of age.

§For all products used, consult the manufacturers' package enclosures for instructions regarding storage, handling, dosage, and administration. Immunobiologics prepared by different manufacturers can vary, and those of the same manufacturer can change from time to time. The package inserts are useful references for specific products, but they may not always be consistent with current ACIP and American Academy of Pediatrics immunization schedules.

¶DTP = Diphtheria and Tetanus Toxoids and Pertussis Vaccine, Adsorbed. DTP may be used up to the seventh birthday. The first dose can be given at 6 weeks of age and the second and third doses given 4–8 weeks after the preceding dose.

**OPV = Poliovirus Vaccine Live Oral, Trivalent: contains poliovirus types 1, 2, and 3.

††Provided at least 6 months have elapsed since DTP#3 or, if fewer than 3 doses of DTP have been received, at least 6 weeks since the last previous dose of DTP or OPV. MMR vaccine should not be delayed to allow simultaneous administration with DTP and OPV. Administering MMR at 15 months and DTP#4 and OPV#3 at 18 months continues to be an acceptable alternative.

§§MMR = Measles, Mumps, and Rubella Virus Vaccine, Live. Counties that report ≥5 cases of measles among preschool children during each of the last 5 years should implement a routine 2-dose measles vaccination schedule for preschoolers. The first dose should be administered at 9 months or the first health-care contact thereafter. Infants vaccinated before their first birthday should receive a second dose at about 15 months of age. Single-antigen measles vaccine should be used for children aged <1 year and MMR for children vaccinated on or after their first birthday. If resources do not allow a routine 2-dose schedule, an acceptable alternative is to lower the routine age for MMR vaccination to 12 months.

¶¶HbCV = Vaccine composed of Haemophilus influenzae b polysaccharide antigen conjugated to a protein carrier. Children <5 years of age previously vaccinated with polysaccharide vaccine between the ages of 18 and 23 months should be revaccinated with a single dose of conjugate vaccine if at least 2 months have elapsed since the receipt of the polysaccharide vaccine.

***If HbCV is not available, an acceptable alternative is to give Haemophilus influenzae b polysaccharide vaccine (HbPV) at age ≥24 months. Children at high risk for *Haemophilus influenzae* type b disease where conjugate vaccine is not available may be vaccinated with HbPV at 18 months of age and revaccinated at 24 months.

†††Up to the seventh birthday.

§§§Td = Tetanus and Diphtheria Toxoids, Adsorbed (for use in persons aged ≥7 years): contains the same amount of tetanus toxoid as DTP or DT but a reduced dose of diphtheria toxoid.

Minimum age for initial vaccination and minimum interval between vaccine doses, by type of vaccine

Vaccine	Minimum *age* for first dose*	Minimum *interval* from dose 1 to 2*	Minimum *interval* from dose 2 to 3*	Minimum *interval* from dose 3 to 4*
DTP (DT)†	6 weeks§	4 weeks	4 weeks	6 months
Combined DTP-Hib	6 weeks	1 month	1 month	6 months
DTaP*	15 months			6 months
Hib (primary series)				
HbOC	6 weeks	1 month	1 month	¶
PRP-T	6 weeks	1 month	1 month	¶
PRP-OMP	6 weeks	1 month	¶	
OPV	6 weeks§	6 weeks	6 weeks	
IPV**	6 weeks	4 weeks	6 months††	
MMR	12 months§§	1 month		
Hepatitis B	birth	1 month	2 months¶¶	

DTP	Diphtheria-tetanus-pertussis
DTaP	Diphtheria-tetanus-acellular pertussis
Hib	*Haemophilus influenza* type b conjugate
IPV	Inactivated poliovirus vaccine
MMR	Measles-mumps-rubella
OPV	Live oral polio vaccine

*These minimum acceptable ages and intervals may not correspond with the optimal recommended ages and intervals for vaccination. See tables 3–5 for the current recommended routine and accelerated vaccination schedules.

†DTaP can be used in place of the fourth (and fifth) dose of DTP for children who are at least 15 months of age. Children who have received all four primary vaccination doses before their fourth birthday should receive a fifth dose of DTP (DT) or DTaP at 4–6 years of age before entering kindergarten or elementary school **and** at least 6 months after the fourth dose. The total number of doses of diphtheria and tetanus toxoids should not exceed six each before the seventh birthday (*14*).

§The American Academy of Pediatrics permits DTP and OPV to be administered as early as 4 weeks of age in areas with high endemicity and during outbreaks.

¶The booster dose of Hib vaccine which is recommended following the primary vaccination series should be administered no earlier than 12 months of age **and** at least 2 months after the previous dose of Hib vaccine (Tables 3 and 4).

**See text to differentiate conventional inactivated poliovirus vaccine from enhanced-potency IPV.

††For unvaccinated adults at increased risk of exposure to poliovirus with <3 months but >2 months available before protection is needed, three doses of IPV should be administered at least 1 month apart.

§§Although the age for measles vaccination may be as young as 6 months in outbreak areas where cases are occurring in children <1 year of age, children initially vaccinated before the first birthday should be revaccinated at 12–15 months of age and an additional dose of vaccine should be administered at the time of school entry or according to local policy. Doses of MMR or other measles-containing vaccines should be separated by at least 1 month.

¶¶This final dose is recommended no earlier than 4 months of age.

APPENDIX D

Adverse Effects of Pertussis and Rubella Vaccines
Executive Summary

Adverse Effects of PERTUSSIS and RUBELLA Vaccines

A Report of the
Committee to Review the Adverse Consequences of
Pertussis and Rubella Vaccines

Christopher P. Howson, Cynthia J. Howe,
and *Harvey V. Fineberg, Editors*

Division of Health Promotion and
Disease Prevention

INSTITUTE OF MEDICINE

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1

Executive Summary

Next to clean water, no single intervention has had so profound an effect on reducing mortality from childhood diseases as has the widespread introduction of vaccines. Immunization, the process in which the body's own protective mechanisms are primed to thwart the invasion or multiplication of pathogens, is effective and relatively inexpensive, simple, and easy to deliver.

The use of vaccines is not entirely without risk, however. Vaccines, including the whole-cell pertussis (whooping cough) vaccine and the rubella (German measles) vaccine, the subjects of this report, typically contain small quantities of material derived from disease-causing organisms. The pertussis vaccine contains dead bacteria and is termed a *killed* or *inactivated vaccine*; the rubella vaccine contains laboratory-weakened live viruses and is termed a *live, attenuated vaccine.*

This study responds to a request to the Institute of Medicine (IOM) to conduct a thorough review of the evidence pertaining to a set of serious adverse events and immunization with pertussis or rubella vaccine. The request to IOM originated in the 1986 National Childhood Vaccine Injury Act (Public Law 99-660), whose primary purpose was to establish a federal compensation scheme for persons potentially injured by a vaccine. Section 312 of Public Law 99-660 called for IOM review of scientific and other information on specific adverse consequences of pertussis and rubella vaccines. The 11-member interdisciplinary committee, constituted

by IOM to conduct this study, recognized that its charge was to focus on questions of causation and not broader topics, such as cost-benefit or risk-benefit analyses of vaccination. These topics are therefore not addressed in the report.

After formation of the committee, additional adverse events were added both by the committee and at the request of the Advisory Commission on Childhood Vaccines. During the 20 months of the study, the committee reviewed altogether *17 adverse events for pertussis vaccine*—infantile spasms; hypsarrhythmia; aseptic meningitis; encephalopathy (including acute encephalopathy and chronic neurologic damage); deaths classified as sudden infant death syndrome (SIDS); anaphylaxis; autism; erythema multiforme or other rashes; Guillain-Barré syndrome (polyneuropathy); peripheral mononeuropathy; hemolytic anemia; juvenile diabetes; learning disabilities and hyperactivity; protracted inconsolable crying or screaming; Reye syndrome; shock and "unusual shock-like state" with hypotonicity, hyporesponsiveness, and short-lived convulsions (usually febrile); and thrombocytopenia—and *3 adverse events for rubella vaccine*—arthritis (acute and chronic); radiculoneuritis and other neuropathies; and thrombocytopenic purpura. Although the committee was not asked expressly to examine febrile seizures, afebrile seizures, or epilepsy in relation to diphtheria-pertussis-tetanus (DPT) vaccine, it did so because these conditions may also be serious and are considered by some to be components of encephalopathy. Conclusions regarding these conditions are given in Chapter 4. The committee's conclusions on acute encephalopathy, also presented in Chapter 4, refer only to conditions diagnosed as encephalopathy, encephalitis, or encephalomyelitis. (For additional information on the committee's charge and the events leading to the enactment of Public Law 99-660, see the Preface and Appendix B, Pertussis and Rubella Vaccines: A Brief Chronology.)

The following three sections of this summary briefly review the methods used by the committee to evaluate the evidence relating the 20 adverse events to pertussis or rubella vaccine, the evidence considered and the conclusions reached for each adverse event, and the research directions recommended by the committee.

METHODOLOGIC CONSIDERATIONS IN EVALUATING THE EVIDENCE

The committee undertook the task of judging whether each of a set of adverse events can occur as a result of exposure to pertussis or rubella vaccine. These judgments have both quantitative and qualitative aspects; they reflect the nature of the exposures, events, and populations at issue; the specific questions to be considered; the characteristics of the evidence examined; and the approach taken to evaluate that evidence. To facilitate the

independent assessment of the committee's conclusions, the committee wishes to make the process of its evaluation as explicit as possible.

The adverse events under consideration by the committee are, in most instances, rare in the exposed population. They also are known to occur in the absence of vaccination, are clinically ill-defined, and are generally of unknown causation in the general population. The exposures—pertussis and rubella vaccinations—are very widespread in the population, so that the absence of exposure may itself require an explanation in the interpretation of comparative studies. These and other features raise a number of difficulties both in the investigation and in the evaluation of the resulting evidence.

The committee considered causal questions of three kinds in connection with adverse events that have been reported to occur after administration of pertussis or rubella vaccine. The first of these questions about exposure to pertussis or rubella vaccine is, in general, *can it cause* the specified adverse condition? For example, can rubella vaccine cause chronic arthritis? If the conclusion is affirmative, a second question becomes pertinent: *How frequently does it cause* that condition? Or, how frequently is arthritis a result of rubella vaccination? The third question, which applies to a particular instance or case of an adverse event, is *did it cause* that specific event? Or, did rubella vaccine cause this particular individual to develop arthritis? The committee has undertaken its evaluation from a neutral posture, presuming neither the existence nor the absence of association between these vaccines and the events under consideration.

The identification and acquisition of the relevant evidence were major tasks of the committee throughout the course of its work. The preponderance of this material comprised either reports of controlled, observational epidemiologic studies (case-comparison or cohort studies) or uncontrolled case reports or case series. There was no experimental evidence, whether in humans or animals, that clearly proved or disproved a causal relation. Each study or report reviewed by the committee was first assessed individually and then, as appropriate, incorporated into the collective results that underlie the committee's conclusions.

Both quantitative and qualitative approaches to integration of the evidence were utilized. Formal meta-analysis was applied when it was feasible and appropriate. All of the studies were assessed insofar as possible with respect to the roles of error, bias, confounding, and chance in producing the observed results. Several considerations bearing on the inference that an association may reflect a true causal relation were also included in the committee's evaluation of the overall body of evidence pertaining to each type of adverse event under review. These included the strength of association, temporal relation between exposure and event, consistency of results between studies, specificity of the relation between exposure and event, and biologic plausibility of such a relation.

SUMMARY AND CONCLUSIONS

Table 1-1 summarizes the categories of evidence reviewed for each adverse event and the respective contribution of each to the committee's judgments about causation. The evidence is organized under five headings: (1) human experiments; (2) animal experiments; (3) case-comparison, cohort, and other controlled studies, (4) case reports and case series; and (5) biologic plausibility. Methods for interpreting evidence in the first four categories are discussed in Chapter 3. The fifth category, biologic plausibility, includes background knowledge concerning the pathophysiology of an adverse event, attributes of a particular vaccine, or other biologic information derived from research in such areas as immunology and physiology. The evidence in these five categories, elaborated in the body of the report, forms the basis of the committee's conclusions.

Where evidence was available in a particular category, the committee judged whether that evidence was generally supportive or not supportive of causation or whether it was insufficient for a determination. For example, where there were relevant controlled studies which, overall, found relative risks greater than 1, the evidence was classified as "supportive of causation." Blanks for any given category of evidence indicate that evidence of that type was lacking. It is important to note that any one category of evidence generally was not sufficient in itself to support a conclusion of causality, since other aspects of the evidence, including the details of the results and the number and quality of contributing studies, as well as the assessment of the other categories of evidence, were also considered in the evaluation.

Table 1-2 summarizes the committee's conclusions about the 20 adverse events evaluated in this report. As shown in the table, the committee found it convenient to organize its conclusions about the adverse events into five categories. These categories reflect the strength and direction of the conclusions about the causal relations between DPT or rubella vaccine and the 20 adverse events evaluated in the report. The bases of these conclusions are discussed in Chapters 4 through 7 of the report. Conclusions on rubella vaccine apply to the RA 27/3 rubella strain currently in use. Evidence does not differentiate between DPT vaccine and the pertussis component of DPT vaccine, except in the case of protracted crying (see below). As shown in Table 1-2, the committee found:

- no evidence bearing on a causal relation between DPT vaccine and autism;
- insufficient evidence to indicate a causal relation between DPT vaccine and aseptic meningitis, chronic neurologic damage, erythema multiforme or other rash, Guillain-Barré syndrome, hemolytic anemia, juvenile diabetes, learning disabilities and attention deficit disorder, peripheral mononeurop-

TABLE 1-1 Categories of Evidence Reviewed for Each Adverse Event: Is the Evidence Supportive of Causation?[a]

Vaccine and Adverse Event (Chapter of Report)	Human Experiments			Animal Experiments			Case-Comparison, Cohort, and Other Controlled Studies			Case Reports and Case Series			Biologic Plausibility		
	Yes[b]	?[c]	No[d]	Yes	?	No	Yes	?	No	Yes	?	No	Yes	?	No
DPT															
Infantile spasms (4)									X		X				
Hypsarrhythmia (4)			X								X				
Aseptic meningitis (4)								X			X				
Acute encephalopathy[e] (4)					X		X			X				X	
Chronic neurologic damage (4)					X			X			X			X	
Sudden infant death syndrome (5)									X		X				
Anaphylaxis (6)					X			X		X			X		
Autism (6)															
Erythema multiforme or other rash (6)											X		X		
Guillain-Barré syndrome (polyneuropathy) (6)											X				
Peripheral mononeuropathy (6)											X				
Hemolytic anemia (6)											X		X		
Juvenile diabetes (6)					X			X			X				
Learning disabilities and hyperactivity (6)									X		X				
Protracted inconsolable crying and screaming (6)							X			X			X		
Reye syndrome (6)								X				X			

TABLE 1-1 *Continued*

Vaccine and Adverse Event (Chapter of Report)	Human Experiments			Animal Experiments			Case-Comparison, Cohort, and Other Controlled Studies			Case Reports and Case Series			Biologic Plausibility		
	Yes[b]	?[c]	No[d]	Yes	?	No	Yes	?	No	Yes	?	No	Yes	?	No
Shock and "unusual shock-like state" (6)								X		X				X	
Thrombocytopenia (6)											X				
RA 27/3 Rubella															
Arthritis (7)															
Acute	X						X			X			X		
Chronic		X								X			X		
Radiculoneuritis and other neuropathies (7)											X		X		
Thrombocytopenic purpura (7)											X		X		

[a]Blanks for any given category of evidence indicate that evidence of this kind is lacking.
[b]Yes, Evidence of this kind is supportive of causation.
[c]?, Evidence of this kind cannot be classified either as supportive or as not supportive of causation.
[d]No, Evidence of this kind is not supportive of causation.
[e]Defined in controlled studies reviewed as encephalopathy, encephalitis, or encephalomyelitis.

TABLE 1-2 Summary of Conclusions by Adverse Event for DPT[a] and RA 27/3 MMR[b] Vaccines

Conclusion	Adverse Events Reviewed	
	DPT Vaccine	RA 27/3 Rubella Vaccine
1. No evidence bearing on a causal relation[c]	Autism	
2. Evidence insufficient to indicate a causal relation[d]	Aseptic meningitis Chronic neurologic damage Erythema multiforme or other rash Guillain-Barré syndrome Hemolytic anemia Juvenile diabetes Learning disabilities and attention-deficit disorder Peripheral mononeuropathy Thrombocytopenia	Radiculoneuritis and other neuropathies Thrombocytopenic purpura
3. Evidence does not indicate a causal relation[e]	Infantile spasms Hypsarrythmia Reye syndrome Sudden infant death syndrome	
4. Evidence is consistent with a causal relation[f]	Acute encephalopathy[g] Shock and "unusual shock-like state"	Chronic arthritis
5. Evidence indicates a causal relation[h]	Anaphylaxis Protracted, inconsolable crying	Acute arthritis

[a]Evidence does not differentiate between DPT vaccine and the pertussis component of DPT vaccine except in the case of protracted, inconsolable crying where the evidence implicates the pertussis component specifically.

[b]RA 27/3 MMR, Trivalent measles-mumps-rubella vaccine containing the RA 27/3 rubella strain.

[c]No category of evidence was found bearing on a judgment about causation (all categories of evidence left blank in Table 1-1).

[d]Relevant evidence in one or more categories was identified but was judged to be insufficient to indicate whether or not a causal relation exists (no category of evidence checked as supporting causation in Table 1-1; exceptions are this designation under biologic plausibility for erythema multiforme and hemolytic anemia).

[e]The available evidence, on balance, does not indicate a causal relation (one or more categories of evidence checked as not supporting causation in Table 1-1, with evidence supporting causation being either absent or outweighed by the other evidence).

[f]The available evidence, on balance, tends to support a causal relation (one or more categories of evidence checked as supporting causation in Table 1-1, with evidence checked as insufficient or not supporting causation being absent or outweighed by the other evidence).

[g]Defined in controlled studies reviewed as encephalopathy, encephalitis, or encephalomyelitis.

[h]The available evidence, on balance, supports a causal relation, and the evidence is more persuasive than that for conclusion 4 above (the categories of evidence are coded similarly to those in conclusion 4, with evidence checked as insufficient or not supporting causation in Table 1-1 being absent or less than for 4).

athy, or thrombocytopenia, and between the currently used rubella vaccine (RA 27/3) and radiculoneuritis and other neuropathies or thrombocytopenic purpura;

- that the evidence does not indicate a causal relation between DPT vaccine and infantile spasms, hypsarrythmia, Reye syndrome, or SIDS;
- that the evidence is consistent with a causal relation between DPT vaccine and acute encephalopathy and shock and "unusual shock-like state," and between RA 27/3 rubella vaccine and chronic arthritis; and
- that the evidence indicates a causal relation between DPT vaccine and anaphylaxis, between the pertussis component of DPT vaccine and protracted, inconsolable crying, and between RA 27/3 rubella vaccine and acute arthritis.[1]

RESEARCH NEEDS

In the course of its review, the committee encountered many gaps and limitations in knowledge bearing directly and indirectly on the safety of vaccines. These include inadequate understanding of the biologic mechanisms underlying adverse events following natural infection or immunization, insufficient or inconsistent information from case reports and case series, inadequate size or length of follow-up of many population-based epidemiologic studies, and limited capacity of existing surveillance systems of vaccine injury to provide persuasive evidence of causation. The committee found few experimental studies published in relation to the number of epidemiologic studies published. Clearly, if research capacity and accomplishment in these areas are not improved, future reviews of vaccine safety will be similarly handicapped.

With respect to pertussis and rubella vaccines, careful review is needed to identify what sorts of questions might be best answered by further investigations and which kinds of studies could be carried out economically. The availability and introduction of new forms of pertussis vaccine, for example, could offer valuable opportunities for comparison of vaccine safety as well as efficacy. The committee's experience points to fresh possibilities and to the need for such a review.

[1] The available evidence is consistent with a causal relation, but, on balance, is more persuasive than that in the previous bullet.

APPENDIX E

Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality
Executive Summary

Adverse Events Associated with CHILDHOOD VACCINES

Evidence Bearing on Causality

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Executive Summary

"Our aim, therefore, must be to study these [complications] as fully as possible in the confident expectation that, as in other branches of science, knowledge will bring enlightenment" (Wilson, 1967).

Childhood immunization has been one of the foremost public health measures of the twentieth century. It has allowed control and prevention of many diseases from which morbidity and mortality can be staggering. Medical personnel in the United States currently rarely see a case of the infectious diseases against which the vaccines are directed. Yet, recent measles epidemics on college campuses and in inner cities suggest that vaccine-preventable disease is not to be ignored. The first health initiative of the new presidential administration was to increase funding for childhood immunization programs to boost vaccination rates in the United States, particularly for children under age 2 years.

BACKGROUND AND HISTORY

The public policy debate regarding immunization stretches beyond the question of how to meet the goals of universal immunization. Concern over the safety of pertussis vaccine was long-standing in Great Britain by the time of the 1982 airing in the United States of a documentary entitled "DPT: Vaccine Roulette" (WRC-TV, 1982) and the 1985 publication of *DPT: A Shot in the Dark* (Coulter and Fisher, 1985). Concern has stretched to other vaccines and has spawned the formation of groups of interested citizens throughout the United States, for example, National Vaccine Information Center/Dissatisfied Parents Together, Determined Parents to Stop Hurting Our Tots, Concerned Health Professionals and Others, and Parents

Concerned About the Safety of Vaccines. More articles and books have been published (e.g., Coulter, 1990; Miller, 1992) to alert the public to the potential risks of vaccination.

In 1986, the U.S. Congress passed the National Childhood Vaccine Injury Act (NCVIA; P.L. 99-660) in response to worries about the safety of currently licensed childhood vaccines and in response to the economic pressures that were threatening the integrity of childhood immunization programs. The litigation costs associated with claims of damage from vaccines had forced several companies to end their vaccine research and development programs as well as to stop producing already licensed vaccines. The NCVIA was an attempt to encourage and ensure vaccine production by creating a no-fault compensation program (the National Vaccine Injury Compensation Program) as a required first resort for those who believed that they or their children had been injured by certain vaccines. The need for a compensation program had long been recognized, and several groups had proposed possible mechanisms for compensating people believed to be injured by vaccination (Institute of Medicine, 1985; Office of Technology Assessment, 1980). This program was envisioned to alleviate, but not completely eliminate, manufacturer liability and encourage research and development of more and safer vaccines. The compensation program is administered by the federal government and is financed by an excise tax on the sale of vaccines covered by the program (Iglehart, 1987; Mariner, 1992).

In addition to establishing the compensation program, the NCVIA set forth other vaccine-related efforts to be carried out by the U.S. Department of Health and Human Services, including mandatory reporting of specific adverse events following childhood immunizations against diphtheria, tetanus, pertussis, measles, mumps, rubella, and polio (see box entitled The Vaccine Injury Table in Chapter 10); voluntary reporting of any reaction to any immunization to the Vaccine Adverse Event Reporting System (see Chapter 10 for a discussion of this passive surveillance system and Figure B-1 for a copy of the reporting form); the creation of a National Vaccine Program Office to coordinate federal vaccine initiatives and to help meet immunization coverage goals; the establishment of advisory groups to the National Vaccine Program and the National Vaccine Injury Compensation Program; and better communication of the potential risks of vaccines through public information pamphlets that are distributed at the time of vaccination (under the direction of the Centers for Disease Control and Prevention) and changes in vaccine package inserts (under the direction of the U.S. Food and Drug Administration).

The NCVIA also mandated that the Secretary of the U.S. Department of Health and Human Services enlist the help of the Institute of Medicine (IOM) of the National Academy of Sciences to study the adverse effects of childhood vaccines. The NCVIA called for two specific studies. The first,

mandated under Section 312 of P.L. 99-660, was to address the serious adverse effects of pertussis and rubella vaccines. The Committee to Review the Adverse Consequences of Pertussis and Rubella Vaccines published its findings in 1991 (Institute of Medicine, 1991). Appendix A contains the Executive Summary of that report.

The second study, mandated under Section 313 of P.L. 99-660, was to review adverse events associated with other vaccines commonly administered during childhood. The Vaccine Safety Committee, which was charged with performing the second study, was convened early in 1992. The results of that inquiry are provided in this report.

THE CHARGE TO THE COMMITTEE

The members of the interdisciplinary, 14-member Vaccine Safety Committee have expertise in such areas as immunology, pediatrics, internal medicine, infectious diseases, neurology, virology, microbiology, epidemiology, and public health. The committee was charged with (1) reviewing the relevant scientific and medical literature on specific risks to children associated with the vaccines or vaccine components directed against tetanus, diphtheria, measles, mumps, polio, *Haemophilus influenzae* type b, and hepatitis B currently licensed for use in the United States and (2) reviewing the available data on specific risk-modifying factors, that is, circumstances under which administration of these vaccines increases the risk of an adverse event, characteristics of groups known to be at increased risk of an adverse event, and timing of vaccination that increases the risk of an adverse event.

Risk-benefit comparisons or recommendations about immunization schedules were not within the charge to the Vaccine Safety Committee. Despite the name of the committee, many aspects of vaccine safety, such as purity standards or production techniques, also were beyond the committee's charge.

Both IOM studies mandated in P.L. 99-660 entailed the evaluation of the weight of scientific and medical evidence bearing on the question of whether a causal relation exists between certain vaccines and specific serious adverse events. Like the Committee to Review the Adverse Consequences of Pertussis and Rubella Vaccines, the Vaccine Safety Committee approached its task from a position of neutrality, presuming neither the presence nor the absence of a causal relation between the vaccines and the adverse events under consideration.

THE STUDY PROCESS

Over the course of 18 months, the committee met six times, reviewed more than 7,000 abstracts of scientific and medical studies, read more than 2,000 published books and articles (including many sources in the non-

English literature), analyzed information from U.S. Public Health Service-administered reporting systems for adverse reactions to vaccines, and considered material submitted by interested parties. The committee solicited input from scientists who were invited to participate in two open scientific meetings and from other interested parties at two open public meetings. Details regarding how the committee gathered information are given in Appendix B. All salient information from those reviews is contained in this report.

P.L. 99-660 stated that the review was to include those vaccines covered by the National Vaccine Injury Compensation Program. *Haemophilus influenzae* type b (Hib) and hepatitis B vaccines were added for consideration because of the increasing use of these vaccines and the supposition that in the near future they could be mandatory vaccines covered by the National Vaccine Injury Compensation Program. The list of adverse events investigated for this report derived primarily from negotiations with representatives of the U.S. Public Health Service. However, preliminary investigations into additional adverse events were prompted by queries from interested parties or committee members. After considering the information from these preliminary investigations, the committee added several vaccine-adverse event relations to the original list. Table B-1 in Appendix B contains a complete listing of the specific vaccine-adverse event relations under study.

The report begins with background information. Chapter 2 contains an in-depth discussion of the approach used by the committee to weight the evidence and assess causality. Information on the neurologic disorders and immunologic reactions discussed in much of the report is contained in Chapters 3 and 4. Chapters 5 through 9 include the vaccine-specific evidence and conclusions. All information (evidence, causality argument, and conclusions) regarding death as an adverse event associated with vaccination is contained in Chapter 10.

Adverse Effects of Pertussis and Rubella Vaccines (Institute of Medicine, 1991), the report of the predecessor IOM committee, provides an in-depth review of the literature concerning the adverse events associated with diphtheria and tetanus toxoids and pertussis vaccine (DPT), as well as pertussis vaccine, and should be referred to for conclusions regarding DPT. Appendix A contains the Executive Summary of that report. The charge to the Vaccine Safety Committee was to examine adverse events associated with tetanus toxoid as well as tetanus and diphtheria toxoid combination preparations. The committee reviewed data concerning DPT if the data also concerned diphtheria and tetanus toxoids for pediatric use (DT); however, it was beyond the committee's scope to make conclusions about pertussis vaccine or DPT.

The IOM Committee to Review the Adverse Consequences of Pertussis

and Rubella Vaccines made determinations of causality only for rubella vaccine and the rubella vaccine component of multivalent vaccines, but not for measles-mumps-rubella vaccine (MMR). Thus, the Vaccine Safety Committee reviewed data regarding immunization with MMR as well as data on monovalent measles and mumps preparations. The committee has made separate determinations of causality for the measles and mumps vaccine components for the adverse events for which data were available, particularly if measles or mumps vaccine-strain virus was isolated from the patient. In circumstances in which a causality assessment specific to monovalent measles or mumps vaccine was not possible, this is stated in the conclusion regarding that specific adverse event.

In circumstances in which the committee determined that a component of a multivalent preparation was causally related to a specific adverse event, but there is no direct experience of such an adverse event being caused by the multivalent preparation, the committee states this, but judges that the combined preparation also is causally related to that adverse event.

Many case reports described an adverse event(s) in a patient who received more than one vaccine. A common combination, as a result of the immunization schedules recommended in the United States, is DPT, oral polio vaccine, and Hib vaccine. Assessment of causality in those reports was more difficult than if the patient had received only one vaccine or vaccine component, but the committee considered that the reports could be theoretically supportive of causality for the combination but not in themselves sufficient to allow a firm judgment regarding causality.

CAUSALITY AND WEIGHT OF EVIDENCE

As discussed in detail in Chapter 2, the committee considered four types of evidence: biologic plausibility; case reports, case series, and uncontrolled observational studies; controlled observational studies; and controlled clinical trials. The committee used qualitative and quantitative approaches to weigh each type of evidence. Table 1-1 contains a summary of the different types of evidence for every vaccine-adverse event relation studied. The committee believes that although it is plausible that there is a causal relation between any of the vaccine-adverse event associations under review, plausibility has been demonstrated only for certain ones of these. Therefore, information on the plausibility of a causal relation was classified in Table 1-1 as either theoretical only or as demonstrated. The other types of evidence were classified in Table 1-1 as nonexistent, indeterminate, or as weighing, on the whole, for or against a determination of a causal relation. The consideration of all four types of evidence as a whole led to a conclusion of the final weight of evidence regarding causality. Table 1-2 contains these conclusions.

TABLE 1-1 Summary of the Evidence For or Against a Determination of a Causal Relation[a]

Vaccine and Adverse Event	Biologic Plausibility[b]	Case Reports, Case Series, and Uncontrolled Observational Studies	Controlled Observational Studies and Controlled Clinical Trials
Diphtheria and Tetanus Toxoids[c]			
Encephalopathy	Demonstrated	Indeterminate	Against (DT) No data (Td, T)
Infantile spasms[d] (DT only)	Theoretical only	No data	Against
Residual seizure disorders other than infantile spasms	Theoretical only	Indeterminate (DT, T) No data (Td)	No data
Demyelinating diseases of the central nervous system	Demonstrated	For	No data
Guillain-Barré syndrome	Demonstrated	For (T) Indeterminate (DT, Td)	No data
Mononeuropathy	Theoretical only	Indeterminate (T, Td) No data (DT)	No data
Brachial neuritis	Theoretical only	For (T) Indeterminate (Td) No data (DT)	No data

Arthritis	Theoretical only	Indeterminate	No data
Erythema multiforme	Theoretical only	Indeterminate (DT, Td) No data (T)	No data
Anaphylaxis	Demonstrated	For (T) Indeterminate (DT, Td)	No data
Death from SIDS (DT only)[e]	Theoretical only	Indeterminate	Against
Measles Vaccine[f]			
Encephalopathy	Demonstrated	Indeterminate	Indeterminate
Subacute sclerosing panencephalitis	Demonstrated	Indeterminate	Indeterminate
Residual seizure disorder	Demonstrated	Indeterminate	No data
Sensorineural deafness	Theoretical only	Indeterminate (MMR)	No data
Optic neuritis	Demonstrated	Indeterminate	No data
Transverse myelitis	Demonstrated	Indeterminate	No data
Guillain-Barré syndrome	Demonstrated	Indeterminate	No data
Thrombocytopenia	Demonstrated	Indeterminate (measles) For (MMR)	Indeterminate (measles) No data (MMR)
Insulin-dependent diabetes mellitus	Theoretical only	Indeterminate	Indeterminate

continued

TABLE 1-1 *(continued)*

Vaccine and Adverse Event	Biologic Plausibility[b]	Case Reports, Case Series, and Uncontrolled Observational Studies	Controlled Observational Studies and Controlled Clinical Trials
Anaphylaxis	Theoretical only	For	No data
Death from vaccine-strain viral infection[f]	Demonstrated	For	No data
Mumps Vaccine[g]			
Encephalopathy	Demonstrated	Indeterminate	No data
Aseptic meningitis	Demonstrated	Indeterminate	No data
Residual seizure disorder	Theoretical only	No data	No data
Neuropathy	Theoretical only	No data	No data
Sensorineural deafness	Demonstrated	Indeterminate (MMR)	No data
Insulin-dependent diabetes mellitus	Demonstrated	Indeterminate	Indeterminate
Sterility	Demonstrated	No data	No data
Thrombocytopenia	Demonstrated	Indeterminate	No data
Anaphylaxis	Theoretical only	Indeterminate (MMR)	No data

Polio Vaccine (OPV and IPV)[g]			
Guillain-Barré syndrome	Demonstrated (OPV) Theoretical only (IPV)	For (OPV) Indeterminate (IPV)	For (OPV) No data (IPV)
Transverse myelitis	Demonstrated (OPV) Theoretical only (IPV)	Indeterminate (OPV) No data (IPV)	No data
Poliomyelitis (OPV only)	Demonstrated	For	No data
Thrombocytopenia (IPV)	Theoretical only	No data	No data
Anaphylaxis (IPV)	Theoretical only	No data	No data
Death from SIDS[e]	Theoretical only	Indeterminate	Indeterminate
Death from vaccine-strain viral infection, including from paralytic poliomyelitis (OPV only)[e]	Demonstrated	For	No data
Hepatitis B Vaccine			
Guillain-Barré syndrome	Demonstrated	Indeterminate	No data
Demyelinating diseases of the central nervous system	Demonstrated	Indeterminate	No data
Arthritis	Demonstrated	Indeterminate	No data
Anaphylaxis	Theoretical only	For	No data
Death from SIDS[e]	Theoretical only	Indeterminate	No data

continued

TABLE 1-1 *(continued)*

Vaccine and Adverse Event	Biologic Plausibility[b]	Case Reports, Case Series, and Uncontrolled Observational Studies	Controlled Observational Studies and Controlled Clinical Trials
Haemophilus influenzae type b Vaccine			
Guillain-Barré syndrome	Theoretical only	Indeterminate	No data
Transverse myelitis	Theoretical only	Indeterminate	No data
Thrombocytopenia	Theoretical only	Indeterminate	Indeterminate
Susceptibility to early Hib disease[b]	Demonstrated	Indeterminate	For (PRP) Against (conjugated)
Anaphylaxis	Theoretical only	Indeterminate	No data
Death from SIDS[c]	Theoretical only	Indeterminate	No data

[a]*Indeterminate* indicates that there is evidence in this category, but the committee did not consider that, on the whole, it weighed either for or against a causal relation. *No data* indicates that the committee did not find data of this type directly bearing on a causal relation between the vaccine and the adverse event.

[b]The committee considered all adverse events to be theoretically plausible and, therefore, classified plausibility in support of causality as either theoretical only or demonstrated. Demonstrated biologic plausibility refers to information on the known effects of the natural disease against which the vaccine is given and the results of animal experiments and in vitro studies.

[c]Unless noted otherwise, the classification for tetanus toxoid (T), diphtheria-tetanus toxoid for pediatric use (DT), and tetanus-diphtheria toxoid for adult use (Td) is the same. The committee was not charged with assessing monovalent diphtheria toxoid or the combined diphtheria and tetanus toxoids and pertussis vaccine (DPT). In Appendix A, see the Executive Summary of *Adverse Effects of Pertussis and Rubella Vaccines* for conclusions about DPT.

[d]Infantile spasms occur only in the age group that receives DT but not Td or T. A possible causal relation between infantile spasms and Td and T was not examined.

[e]In this table, the committee summarizes the data regarding the causal relation between the vaccine and only those deaths that are classified as sudden infant death syndrome (SIDS) or that are a consequence of vaccine-strain viral infection. SIDS occurs primarily in infants too young to receive tetanus and diphtheria toxoids for adult use, measles vaccine, mumps vaccine, or usually, tetanus toxoid. Therefore, a relation between these vaccines and SIDS was not assessed. If the evidence favors the acceptance of (or establishes) a causal relation between a vaccine and an adverse event, and if that adverse event can be fatal, then in the committee's judgment the evidence favors the acceptance of (or establishes) a causal relation between the vaccine and death from the adverse event. Direct evidence regarding death in association with a potentially fatal adverse event that itself is causally related to the vaccine is limited to tetanus-diphtheria toxoid for adult use and Guillain-Barré syndrome, tetanus toxoid and anaphylaxis, and oral polio vaccine (OPV) and poliomyelitis. Direct evidence regarding death in association with a potentially fatal adverse event that itself is causally related to the vaccine is lacking for measles vaccine and anaphylaxis, MMR and anaphylaxis, OPV and Guillain-Barré syndrome, hepatitis B vaccine and anaphylaxis, and *Haemophilus influenzae* type b unconjugated PRP vaccine and early-onset *Haemophilus influenzae* type b disease in children age 18 months or older who receive their first Hib immunization with unconjugated PRP vaccine. See Chapter 10 for details. The data are indeterminate regarding the causal relation between the vaccine and causes of death other than those discussed above. Data regarding death as an adverse consequence of the vaccines under review are discussed in Chapter 10 rather than in the vaccine-specific chapters.

[f]The committee was charged with assessing the causal relation between several adverse events and measles vaccine or mumps vaccine. The committee was not charged with assessing monovalent rubella vaccine. In Appendix A, see the Executive Summary of *Adverse Effects of Pertussis and Rubella Vaccines* for conclusions regarding rubella vaccine. (MMR) indicates that the data derive exclusively from the multivalent preparation.

[g]OPV is oral polio vaccine; IPV is inactivated polio vaccine.

[h]The committee assessed data regarding the increased susceptibility to *Haemophilus influenzae* type b disease within 7 days of immunization with *Haemophilus influenzae* type b vaccine. For this adverse event only, the committee was able to separate the data regarding the unconjugated (PRP) vaccine from the data regarding the conjugated vaccines.

TABLE 1-2 Conclusions Based on the Evidence Bearing on Causality

DT/Td/T	Measles[a]	Mumps[a]	OPV/IPV[b]	Hepatitis B	*H. influenzae* type b
Category 1: No Evidence Bearing on a Causal Relation					
		Neuropathy	Transverse myelitis (IPV)		
		Residual seizure disorder	Thrombocytopenia (IPV)		
			Anaphylaxis (IPV)		
Category 2: The Evidence Is Inadequate to Accept or Reject a Causal Relation					
Residual seizure disorder other than infantile spasms	Encephalopathy	Encephalopathy	Transverse myelitis (OPV)	Guillain-Barré syndrome	Guillain-Barré syndrome
Demyelinating diseases of the central nervous system	Subacute sclerosing panencephalitis	Aseptic meningitis	Guillain-Barré syndrome (IPV)	Demyelinating diseases of the central nervous system	Transverse myelitis
Mononeuropathy	Residual seizure disorder	Sensorineural deafness (MMR)	Death from SIDS[c]	Arthritis	Thrombocytopenia
Arthritis	Sensorineural deafness (MMR)	Insulin-dependent diabetes mellitus		Death from SIDS[c]	Anaphylaxis
	Optic neuritis	Sterility			Death from SIDS[c]

Erythema multiforme	Transverse myelitis	Thrombocytopenia		
	Guillain-Barré syndrome	Anaphylaxis[d]		
	Thrombocytopenia			
	Insulin-dependent diabetes mellitus			
Category 3: The Evidence Favors Rejection of a Causal Relation				
Encephalopathy[c]				Early onset *H. influenzae* b disease (conjugate vaccines)
Infantile spasms (DT only)[f]				
Death from SIDS (DT only)[f,e]				
Category 4: The Evidence Favors Acceptance of a Causal Relation				
Guillain-Barré syndrome[b]	Anaphylaxis[d]		Guillain-Barré syndrome (OPV)	Early-onset *H. influenzae* b disease in children age 18 months or older who receive their first Hib immunization with unconjugated PRP vaccine
Brachial neuritis[b]				

continued

TABLE 1-2 *(continued)*

DT/Td/T	Measles[a]	Mumps[a]	OPV/IPV[b]	Hepatitis B	*H. influenzae* type b
Category 5: The Evidence Establishes a Causal Relation					
Anaphylaxis[h]	Thrombocytopenia (MMR)		Poliomyelitis in recipient or contact (OPV)	Anaphylaxis	
	Anaphylaxis (MMR)[d]				
	Death from measles vaccine-strain viral infection[c,i]		Death from polio vaccine-strain viral infection[c,i]		

[a]If the data derive from a monovalent preparation, then in the committee's judgment the causal relation extends to multivalent preparations. If the data derive exclusively from MMR, that is so indicated by (MMR). In the absence of any data on the monovalent preparation, in the committee's judgment the causal relation determined for the multivalent preparations does not extend to the monovalent components.

[b]For some adverse events, the committee was charged with assessing the causal relation between the adverse event and only oral polio vaccine (OPV) (paralytic and nonparalytic poliomyelitis) or only inactivated polio vaccine (IPV) (anaphylaxis and thrombocytopenia). If the conclusions are different for OPV than for IPV for the other adverse events, that is so noted.

[c]This table lists weight-of-evidence determinations only for deaths that are classified as SIDS and deaths that are a consequence of vaccine-strain viral infection. However, if the evidence favors the acceptance of (or establishes) a causal relation between a vaccine and an adverse event, and that adverse event can be fatal, then in the committee's judgment the evidence favors the acceptance of (or establishes) a causal relation between the vaccine and death from the adverse event. Direct evidence regarding death in association with a vaccine-associated adverse event is limited to tetanus-diphtheria toxoid for adult use (Td) and Guillain-Barré syndrome, tetanus toxoid and anaphylaxis, and OPV and poliomyelitis. Direct evidence regarding death in association with a potentially fatal adverse event that itself is causally related to the vaccine is lacking for measles vaccine and anaphylaxis, MMR and anaphylaxis, OPV and Guillain-Barré syndrome, hepatitis B vaccine and anaphylaxis, and *H. influenzae* type b unconjugated PRP vaccine and early-onset *H. influenzae* type b disease in children age 18 months or older who receive their first Hib immunization with unconjugated PRP vaccine. See Chapter 10 for details.

[d]The evidence that establishes a causal relation for anaphylaxis derives from MMR. The evidence regarding monovalent measles vaccine favors acceptance of a causal relation, but are less convincing, mostly because of incomplete documentation of symptoms or the possible attenuation of symptoms by medical intervention.

[e]The evidence derives from studies of diphtheria-tetanus toxoid for pediatric use (DT). If the evidence favors rejection of a causal relation between DT and encephalopathy, then in the committee's judgment the evidence favors rejection of a causal relation between Td and tetanus toxoid and encephalopathy.

[f]Infantile spasms and SIDS occur only in an age group that receives DT but not Td or tetanus toxoid.

[g]The evidence derives mostly from DPT. Because there are supportive data favoring rejection of a causal relation between DT and SIDS as well, if the evidence favors rejection of a causal relation between DPT and SIDS, then in the committee's judgment the evidence favors rejection of a causal relation between DT and SIDS.

[h]The evidence derives from tetanus toxoid. If the evidence favors acceptance of (or establishes) a causal relation between tetanus toxoid and an adverse event, then in the committee's judgment the evidence favors acceptance of (or establishes) a causal relation between DT and Td and the adverse event as well.

[i]The data come primarily from individuals proven to be immunocompromised.

The committee organized these conclusions into five categories. Because some confusion has arisen over the meaning of the category descriptions used by the Committee to Review the Adverse Consequences of Pertussis and Rubella Vaccines, despite extensive explanations in both the footnotes and the text, the Vaccine Safety Committee adopted some minor modifications in wording intended to help in the interpretation of the present report. To facilitate reading by those familiar with the report of the previous committee, the present committee maintained both the number of categories (five) and the order of those categories but modified the wording in an attempt to clarify its meaning. However, the Vaccine Safety Committee (which has some overlap in committee membership and staff with the earlier committee) believes that the categories represent the same concepts intended by the predecessor committee. The categories are:

1. No evidence bearing on a causal relation.
2. The evidence is inadequate to accept or reject a causal relation.
3. The evidence favors rejection of a causal relation.
4. The evidence favors acceptance of a causal relation.
5. The evidence establishes a causal relation.

Chapter 2 contains a discussion of the criteria used by the committee for each determination of the final weight of evidence.

The evidence favors rejection of, favors acceptance of, or establishes a causal relation between a vaccine and an adverse event in approximately one-third of the relations studied. For the other relations the evidence was inadequate to accept or reject a causal relation or there was no evidence bearing on the relation. It is important to note that the use of the term *inadequate* does not necessarily imply that the data were scarce. In some cases the committee identified an abundance of data. However, as a whole, it did not favor either acceptance or rejection of a causal relation. In the lists below, the superscript letters refer to the appropriate notes in Table 1-2. The notes in Tables 1-1 and 1-2 are integral to interpretation of the findings. The committee reached the following conclusions regarding causality.

The evidence favors rejection of a causal relation between:

- diphtheria and tetanus toxoids and encephalopathy,[e] infantile spasms,[f] and death from sudden infant death syndrome (SIDS),[f,g] and
- conjugate Hib vaccines and early-onset Hib disease.

The evidence favors acceptance of a causal relation between:

- diphtheria and tetanus toxoids and Guillain-Barré syndrome[h] and brachial neuritis.[h]
- measles vaccine and anaphylaxis.[d]

- oral polio vaccine and Guillain-Barré syndrome, and
- unconjugated (PRP) Hib vaccine and early-onset Hib disease in children age 18 months or older who receive their first Hib immunization with unconjugated (PRP) vaccine.

The evidence establishes a causal relation between:

- diphtheria and tetanus toxoids and anaphylaxis.[h]
- measles vaccine and death from measles vaccine-strain viral infection.[c,i]
- measles-mumps-rubella vaccine and thrombocytopenia and anaphylaxis.
- oral polio vaccine and poliomyelitis and death from polio-vaccine-strain viral infection,[c,i] and
- hepatitis B vaccine and anaphylaxis.

For the vast majority of vaccine-adverse event relations studied, the data came predominantly from uncontrolled studies and case reports. Most of the pathologic conditions studied are rare in the general population. The risk of developing these conditions because of vaccination would *seem* to be low. Without age-specific incidence rates and relative risk estimates, however, it is not possible to calculate the proportion of individuals whose condition is causally related to a vaccine. When the data permitted, such calculations (i.e., the risk difference or excess risk) were made and can be found in the conclusions in Chapters 5 through 9. Because age-specific incidence rates were not available for many of the pathologic conditions studied and because controlled epidemiologic studies of these relations are lacking, few such estimates could be made.

NEED FOR RESEARCH AND SURVEILLANCE

During its attempt to find evidence regarding causality, the committee identified needs for research and surveillance of adverse events. Work in these areas will help to ensure that all vaccines used are as free from the risk of causing adverse events as possible. Some of the needs identified are for increased surveillance of reports of demyelinating disease and arthritis following hepatitis B vaccination, better follow-up of reports of death and other serious adverse events following vaccination, increased use of large databases (currently used only on a small scale) to supplement passive surveillance reporting systems, and disease registries for the rare pathologic conditions studied by the committee.

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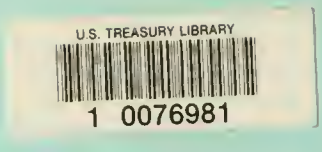

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